

**A 12 MONTH FOLLOW UP OF THE RE-EDUCATION
OF ARM AND HAND FUNCTION FOLLOWING
STROKE (REACH) RANDOMISED CONTROLLED
TRIAL: A MIXED METHODS STUDY**

Helen LUCKIE

School of Health Sciences,
University of Salford, Salford, UK

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List of Abbreviations

ADL	Activities of Daily Living
ARAT	Action Research Arm Test
CCFES	Contralaterally Controlled Functional Electrical Stimulation
CNS	Central Nervous System
CIMT	Constraint Induced Movement Therapy
COPM	Canadian Occupational Performance Measure
CQC	Care Quality Commission
DOH	Department of Health
EBRSR	Evidence Based Review of Stroke Rehabilitation
EMG	Electromyography
ESD	Early Supported Discharge
FES	Functional Electrical Stimulation
FET	Functional Electrical Therapy
FM	Fugl-Meyer Assessment
HFG	Higher Functioning Group
HRQOL	Health Related Quality of Life
IFESS	International Functional Electrical Stimulation Society
K ⁺	Potassium
LFG	Lower Functioning Group
MAL	Motor Assessment Log
MAS	Modified Ashworth Scale
MICD	Minimal Important Clinical Difference
Na ⁺	Sodium
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMES	Neuromuscular Electrical Stimulation
O2PS	Odstock 2 channel Programmable Stimulator
OT	Occupational Therapy
PCT	Primary Care Trust
PIADS	Psychological Impact of Assistive Devices Scale
PwS	Person/ People with Stroke
RCT	Randomised Controlled Trial
REAcH	Re-Education of Arm and Hand function following stroke
RCP	Royal College of Physicians
SIS	Stroke Impact Scale
SSNAP	Sentinel Stroke National Audit Programme
UK	United Kingdom
VR	Virtual Reality
WMFT	Wolf Motor Function Test

Abstract

Functional electrical stimulation (FES) has shown promise as a treatment for upper limb rehabilitation following stroke, although current devices are limited in functionality. To address this a new movement-triggered FES device was developed and trialled in people with chronic stroke in the REACH study.

Studies of long term effects of FES have been limited both in time (up to 9-months post intervention) and scope (focusing only on quantitative outcomes). Therefore, this mixed methods study followed up a sub-set of participants in the REACH study at the Salford site at 12 months post intervention with the aims of: 1. Identifying whether changes in impairment, function and Quality of Life seen during REACH were maintained at 12 months. 2. Whether the changes in outcomes could be attributed to the nature of the intervention. 3. Exploring the experiences of the participants' upper limb post stroke recovery during the REACH study and over the 12 month follow up period.

Measures taken during the REACH study were repeated 12 months following the end of the intervention period, and semi-structured interviews were carried out. Statistical and thematic analysis were used to present data.

The nine participants recruited showed no statistically significant differences in all but two domains of the SIS, participation ($p=0.03$) and recovery ($p = 0.006$) at the end of intervention which were maintained at follow up. Some changes in study measures were seen at an individual level, which in cases were maintained, or showed continued improvement over the 12 month follow up. Thematic analysis identified long term positive outcomes from exercise and FES interventions in chronic stroke as well as non-physical issues which influence upper limb recovery. A degree of mismatch between quantitative and qualitative measures was noted, in line with recent research. Consideration of inclusion of both measures in future studies can assist to fully evaluate the effect of an intervention.

Chapter 1 Introduction

1.1 Background and rationale

Stroke is a leading cause of disability in the UK (Mendis, 2013). Impairment of the upper limb commonly extends into the chronic post-stroke phase, with up to 65% of patients with stroke (PwS) reporting resulting limitations in activities of daily living and participation (Mayo, Wood-Dauphinee, Côté, Durcan, & Carlton, 2002; Winstein et al., 2013). Upper limb impairment is associated with a low level of subjective well-being

(Broeks, Lankhorst, Rumping, & Prevo, 1999) and can negatively influence leisure activities (Sveen, Bautz-Holter, Sodering, Wyller, & Laake, 1999). Exploring the perceptions of PwS reveals stroke has broad impact extending beyond physical issues alone (Graven, Sansonetti, Moloczij, Cadilhac, & Joubert, 2013).

Stroke recovery is a complex process thought to continue for years post stroke, via neuroplastic mechanisms. The recovery process can be influenced by external stimuli, such as rehabilitation interventions (Kwakkel, Kollen, & Lindeman, 2004; Nudo, 2003a, 2003b). Evidence from both animal models and human trials supports relatively high doses of repetitive task practice in rehabilitation interventions to promote neuroplastic changes (Plautz, Milliken, & Nudo, 2000; Pollock et al., 2014). The evidence also suggests that effective practice is characterised by being varied, meaningful and involving a voluntary element on the part of the patient (Krakauer, 2006). The reality of therapy is that it is low in dosage and its content does not align well with the evidence base (Lang et al., 2009; NICE, 2013).

Technology is emerging within rehabilitation as an adjunct to therapy. Functional Electrical Stimulation (FES) has the potential to deliver high intensity task practice, with the added benefit of direct excitation of lower motor neurons. Despite studies being heterogeneous in terms of intervention, dose and measures used, the weight of evidence in both acute and chronic FES studies with PwS suggest that when FES is

combined with task training it can be effective in reducing impairment and increasing function. FES can also allow PwS with a more severe impairment to practice tasks.

Only a small number of rehabilitation and indeed FES studies have followed up participants over a longer term to establish the long term persistence of any changes in impairment or function or quality of life (Knutson et al., 2012; Kraft, Fitts, & Hammond, 1992; Wolf et al., 2008). Even more scarce is data from the perspective of the user. However, user perceptions of technology can contribute valuable feedback in relation to usability and effectiveness (Hughes et al., 2011), and barriers to translation of evidence based technologies (Hughes et al., 2014). As noted above PwS do not view their recovery only from a physical perspective, so the experiences and perceptions of participants within a trial using new technology can be valuable information, towards shaping future rehabilitation for the upper limb.

1.2 Outline of Thesis Structure

1.2.1 Chapter 2

This chapter sets the scene for the thesis by reviewing the incidence and prevalence of stroke, and of upper limb impairments and functional limitations following stroke. The time course of recovery of the upper limb in stroke is reviewed, highlighting evidence showing recovery is possible in chronic stroke. The theoretical basis, evidence base for upper limb treatments and national guidelines are then outlined, and contrasts are drawn with the reality of therapy interventions in the United Kingdom (UK). The section concludes with recent work on prediction of upper limb recovery following stroke and other factors which may influence upper limb recovery.

The perspectives of people with stroke are reviewed, in particular in the concept of recovery is discussed, along with factors involved which are not only physical, but psychological, emotional and social.

Functional electrical stimulation (FES) is introduced and the mechanism of action outlined. Neuroplasticity and motor learning are reviewed as components of the theoretical basis for FES. The evidence supporting use of FES in acute stroke

rehabilitation is briefly presented, with a more in-depth review of the literature in chronic stroke, aligning with the population of this study. This study focuses upon long-term follow up in FES and the lack of evidence in this field is discussed.

This chapter concludes with a summary of the Stroke Association-funded randomised controlled trial (RCT) Accelerometer-triggered functional electrical stimulation for the recovery of upper limb function in chronic stroke patients (short title: Re-Education of Arm and Hand function following stroke, acronym: REAcH), leading to the research aims and objectives.

1.2.2 Chapter 3

This chapter outlines the quantitative methods of the study, including details of design, size of the study, criteria, recruitment, consent and ethical considerations. The outcome measures used in this study are presented along with details of the validity and reliability of each measure. Finally, the data analysis approach is presented.

1.2.3 Chapter 4

This chapter outlines the qualitative methods of the study. It includes the justification for the approach taken and the relevant theoretical underpinning of the methodology chosen. The rationale and development of the data collection tool are presented. Pertinent ethical considerations in addition to those in the previous chapter are outlined, along with the procedure for the interviews. The process of thematic analysis and thematic networks are introduced to guide the reader in the process of reduction of the qualitative data to themes. The chapter concludes with details of the verification process.

1.2.4 Chapter 5

The quantitative results are presented in Chapter 5, including demographics, comparisons of baseline measures of the full REAcH cohort and the follow up study.

1.2.5 Chapter 6

In Chapter 6, the data from interviews with participants are analysed following the process set out in chapter 4. The results of a thematic analysis of the data are presented and conclusions are drawn.

1.2.6 Chapter 7

This chapter synthesises the quantitative and qualitative findings, which are reviewed in relation to the study aims and objectives. The quantitative and qualitative findings are then explored further in relation to individual participants in the study. The limitations within the work are discussed. Finally, conclusions are drawn and future work is discussed.

Chapter 2 Literature Review

2.1 Incidence and Prevalence of Stroke

Each year in the UK around 152,000 people have a stroke (The Stroke Association, 2016). Stroke is the fourth largest cause of death in the UK and second in the world (The Stroke Association, 2016). It is estimated there are approximately 1.2 million people living with stroke in the UK (The Stroke Association, 2016), making stroke the leading cause of adult disability in the UK and the western world (Mendis, 2013).

Stroke incidence fell by 19% from 1990 to 2010 in the UK, but stroke mortality rates also fell by 46% in the same time period (Feigin et al., 2014), meaning that there are now more people living with the long-term consequences of stroke than ever before (Langhorne, Bernhardt, & Kwakkel, 2011).

Stroke also poses a substantial economic burden. For example, in 2008 the cost to the United States was estimated at US\$65 billion (Zhang, Chapman, Plested, Jackson, & Purroy, 2012). The cost to the UK is estimated to be around £9 billion a year (Saka, McGuire, & Wolfe, 2009), and with the increasing numbers of people living with the consequences of stroke, this economic burden is only predicted to increase (Romano, Imrey, & Sacco, 2011).

2.2 Upper Limb After Stroke

2.2.1 Incidence and prevalence of upper limb impairment & functional limitation following stroke

At onset of stroke 77 % have impairments to their upper limb (Lawrence et al., 2001). Winstein et al (2013) report that 65% of people with stroke (PwS) at 6 months post stroke are unable to incorporate the paretic hand effectively into daily activities (Winstein et al., 2013). A large study, involving 434 PwS interviewed at least 6 months post stroke, found that 39% reported limitation in functional activities, 54%

limitations with higher level activities of daily living (ADL) such as housework, and 65% restrictions with their integration back into community activities (Mayo et al., 2002).

Kwakkel et al (2003) found in severely affected PwS, approximately 40% achieved some dexterity at 6 months post stroke (Kwakkel, Kollen, van der Grond, & Prevo, 2003). In mild / moderately affected individuals Nijland et al (2010) found the prognosis to be better with 71% achieving at least some dexterity at 6 months (Nijland, van Wegen, Harmeling-van der Wel, & Kwakkel, 2010).

2.2.2 Time course of recovery of the upper limb following stroke

It has been widely accepted that the rate of recovery from stroke is fastest in the first 3 months. The rate of recovery is reported to slow around 6-months post-stroke. A plateau is often referred to at this point, however as discussed below recovery may continue beyond 6-months (Jorgensen et al., 1995a, 1995b).

In the Copenhagen Stroke Study, Jorgensen et al stratified the 1197 people with acute stroke according to initial severity, using the Scandinavian Neurological Stroke Scale of neurological deficit and the Bartel Index of ADL function as outcome measures (Jorgensen et al., 1995a, 1995b). In 95% of the PwS functional recovery reached the maximum value as assessed by the Bartel Index within 12.5 weeks of stroke onset, with 80% of PwS achieving their best function within 6 weeks. They found the time course of functional recovery was strongly correlated to the initial stroke severity, with best function by Bartel Index reached in 8.5, 13, 17 and 20 weeks for mild, moderate, severe and very severe respectively. The study also reported that no significant improvements were made after these times. In conclusion the study reported that reliable prognoses can be made within 12 weeks of a stroke, and even in very severe PwS no further recovery should be expected after 5 months.

However, since the Copenhagen study, a large body of evidence has been produced that challenges the plateau in recovery around 6-month post stroke, that recovery can occur beyond this point (often referred to as the onset of the chronic stroke phase)

(Dobkin, 2005; Page, Gater, & Bach, 2004; Teasell et al., 2012). The plateau has also been re-interpreted as a cue to vary and progress therapy rather than to cease it (Page et al., 2004). A Cochrane review of interventions aimed at improving upper limb function after stroke found moderate quality evidence of recovery in measures of function in the chronic stroke phase (Pollock et al., 2014). In an analysis of over 125 RCT's robust evidence was found for rehabilitation interventions in chronic stroke (Teasell et al., 2012). For example, analysis of studies into Virtual Reality (VR) also show evidence of functional improvement in patients over one year post-stroke (Laver, George, Thomas, Deutsch, & Crotty, 2011). Of particular note, Constraint Induced Movement Therapy (CIMT) was evaluated in the EXCITE Randomised Controlled Trial (RCT) which showed significant and clinically relevant improvements in upper limb function in the sub-acute / chronic stroke phase. In this trial the participants were between 3 and 9-months post stroke (mean of 184 days post stroke) and received 2 weeks of CIMT with follow up at the 1 and 2 year marks. Improvements seen immediately after the end of the intervention were maintained over follow-up (Wolf et al., 2006; Wolf et al., 2008).

Recent evidence suggests the 'plateau' is conceptually more complex than previously considered. Demain et al (2006) propose that it relates not only to the PwS physical potential, but can also be influenced by how recovery is measured, the intensity and type of therapy, PwS actions and motivation, therapist values and service limitations (Demain, Wiles, Roberts, & McPherson, 2006).

2.2.3 Predictors of recovery

Veerbeek et al (2011), found strong evidence that age and the initial severity are predictors of outcome (Veerbeek, Kwakkel, van Wegen, Ket, & Heymans, 2011). In a review of predictors of upper limb recovery Coupar et al (2012) agree with Veerbeek et al (2011) that initial severity of motor impairment of function is the most important predictive factor (Coupar, Pollock, Rowe, Weir, & Langhorne, 2012). A few authors have investigated motor function such as shoulder abduction and active finger extension and proximal shoulder and elbow control as predictors of regaining dexterity and some function at 6-months (Houwink, Nijland, Geurts, & Kwakkel,

2013; Nijland et al., 2010). Nijland et al (2010) found that those patients who could produce some active finger extension and shoulder abduction on the second day after their stroke, had a 98% chance of having some dexterity at 6 months and 60% showed a full recovery as measured by the Action Research Arm Test (ARAT) (Nijland et al., 2010). However, for those individuals who did not have this level of activity in their upper limb, only 25% regained some dexterity at 6-months. Factors such as age, initial severity and early observations of motor function appear strong predictors of outcome for upper limb recovery. However, as discussed below, therapy interventions also play a role in the recovery of the upper limb.

2.3 Theoretical Basis for Upper Limb Treatments

Stroke recovery is a complex process, and is not fully understood, but current thinking is that it occurs via a mix of spontaneous (non learning dependent processes) and learning-dependent processes (Barnes, Dobkins, & Bogousslavsky, 2005; Langhorne et al., 2011). The early, spontaneous recovery is described as restitution. This term refers to the restoration of the functionality of damaged neural process that is generally independent of external stimuli and includes resolution of oedema (early weeks), reperfusion of the non-infarcted ischemic penumbra (early hours-weeks) and resolution of diaschisis (early days to months).

Central nervous system (CNS) reorganisation or “neuroplasticity” is thought to extend longer than the other processes up to years following a stroke, and is thought to be influenced by external stimuli such as rehabilitation interventions (Kwakkel et al., 2004; Nudo, 2003a, 2003b). Nudo (2003) has suggested that changes that occur during motor learning such as synaptogenesis and synaptic strengthening are likely to be the same type of changes that occur in stroke recovery (Nudo, 2003a). Nudo reports that neuroplasticity after a stroke is based on three concepts, firstly that in a normal brain, skill acquisition of movements is associated with predictable functional changes within the motor cortex. Secondly that injury to the motor cortex from a stroke produces functional changes in the remaining cortical tissue. Thirdly after a cortical stroke, the two observations interact so that re-acquiring motor skills are

associated with functional neurological reorganisation that is occurring in the non-damaged areas of the cortex (Nudo, 2003a).

2.4 What Should Upper Limb Rehabilitation Consist of?

A recent Cochrane review found there was no high-quality evidence found for any interventions that are currently used in routine practice in the UK (Pollock et al., 2014). Moderate-quality evidence was found in support of CIMT, mental practice, mirror therapy, interventions for sensory impairment, virtual reality and a relatively high dose of repetitive task practice (Pollock et al., 2014). Indeed, repetitive task practice is a core part of most evidence-based interventions, including CIMT and technology-supported therapy using virtual reality, robotics or FES. The findings from clinical studies are consistent with reports by Nudo and colleagues that neuroplastic changes occur when new functional skills are learned by repeated practice of functional tasks, not by simply repeating identical non-skilled movements (Nudo, 2003a, 2003b). Work in animal models (Plautz et al., 2000) has also supported the assumption that repetitive motor activity alone does not produce the functional reorganisation of cortical maps needed. Skill acquisition is a prerequisite part of driving plasticity in the motor cortex (Plautz et al., 2000).

There is an emerging consensus on the features of task practice that are thought to be required to drive positive neural and functional changes in the person. These include high intensity practice of varied, meaningful and functionally relevant tasks, as well as active cognitive involvement such as initiation and control of activity (Krakauer, 2006; Shumway-Cook & Woollacott, 2001; van Peppen et al., 2004). Voluntary initiation of the movement promotes sensorimotor integration, intrinsic proprioceptive and sensory feedback which are key elements driving motor learning (Krakauer, 2006; Subramanian, Massie, Malcolm, & Levin, 2010). Extrinsic feedback in the form of knowledge of results and/or performance is another key element of motor learning (Krakauer, 2006; Shumway-Cook & Woollacott, 2001; Subramanian et al., 2010; van Peppen et al., 2004). Task-specific training involves the practice of tasks relevant to daily life and is also seen as an important feature of effective therapy (Pollock et al.,

2014; van Peppen et al., 2004). A recent systematic review and meta-analysis looked at the evidence for physical therapy post stroke and found strong evidence for interventions favouring intensive, high repetitive task-orientated and task-specific training in all phases post-stroke (Veerbeek et al., 2014). The review noted that the intensity of practice is a key factor in meaningful training, and more practice is better. However, it also noted that the effects on function are mostly restricted to the actual functions trained.

A number of studies have explored the dose-response relationship in task-specific practice. Animal studies suggest that to make changes in the primary motor cortex the number of repetitions needs to be in the hundreds (Luke, Allred, & Jones, 2005). Monkeys performed 600 repetitions of a pellet retrieval task per day, to reverse the detrimental changes caused by a cortical lesion (Nudo, Wise, SiFuentes, & Milliken, 1996). A human study investigated the feasibility of translating the animal doses to people with chronic stroke in one-hour training sessions (Birkenmeier, M., & Lang, 2010). The goal of an average of 300 repetitions per session was exceeded with an average of 322. Action Research Arm Test scores improved by an average of 8 points, (above the MICD of 5.7) during the intervention and activity and participation measures both improved, but impairment did not.

2.4.1 Stroke recovery thresholds

The EXCITE study results and associated subsequent studies found evidence to suggest that there may be a definable point at which therapy is no longer beneficial (Schweighofer, Han, Wolf, Arbib, & Winstein, 2009; Wolf et al., 2006). Han et al (2008) hypothesised that if motor retraining after stroke leads to spontaneous use of the paretic arm in everyday life (Han, Arbib, & Schweighofer, 2008), the PwS could enter a ‘virtuous’ circle and therapy could be stopped. However, if the dose of therapy is not sufficient to facilitate the practice and spontaneous use increases above a threshold at which the paretic arm is used in everyday life, then performance in turn will not improve and the patient may develop further compensatory strategies and learned non-use (Han et al., 2008). This work was continued by Schweighofer, Han and colleagues (2009) who following reanalysis of the EXCITE trial data, found there

was a ‘group’ threshold, above which a majority of participants, but not all, improve spontaneously (Schweighofer et al., 2009). Further research is ongoing regarding identifying the threshold.

2.5 The Reality of Therapy Interventions

2.5.1 Guidelines

Stroke rehabilitation is designed to “facilitate restoration of, or adaption to the loss of, physiological or psychological function when reversal of the underlying pathological process is incomplete” (NICE, 2013). Major improvements have been achieved in the medical management of stroke over the past ten to twenty years, including the widespread introduction of stroke units (Royal College of Physicians, 2010). However, improvements in acute care have not yet been matched by progress in delivery of effective post-hospital support (Department of Health, 2010). The National Institute for Health and Care Excellence (NICE) recommends the following rehabilitation programme: “Patients with stroke are offered a minimum of 45 minutes of each active therapy that is required, for a minimum of 5 days a week, at a level that enables the patient to meet their rehabilitation goals for as long as they are continuing to benefit from the therapy and are able to tolerate it.” (NICE, 2013).

With regard to chronic stroke, Royal College of Physicians (RCP) guidelines state that any patient whose situation changes (e.g. new problems emerge or they enter a changed environment) should be offered further assessment by the specialist stroke rehabilitation service (Royal College of Physicians, 2012). A named person and/or contact point should also be identified and communicated to the patient to provide further information and advice if needed. If any patient has residual impairment after the end of initial rehabilitation, they should be offered a formal review at least every 6 months, to consider whether further interventions are warranted, and should be referred for specialist assessment. It also states however that further therapy following a 6-month review should only be offered if clear goals are agreed. Patients should also have their stroke risk factors and prevention plan reviewed at least every year (Intercollegiate Stroke Working Party, 2012).

2.5.2 Reality of stroke therapy

The National Sentinel Stroke Audit from 2014 reports physiotherapy/occupational therapy was provided to patients on 65.3% and 53.8% of in-patient days respectively and the median duration of physiotherapy per day was 33.3 minutes and 40 minutes for occupational therapy (Royal College of Physicians, 2014b), significantly below the recommended intensity discussed above.

McHugh and Swain (2014) compared reported therapy staffing levels and Department of Health (DOH) therapy staffing guidelines (McHugh & Swain, 2014), and found only 42% of units reached DOH guidelines for Physiotherapy, 16% for Speech and language therapy and 84% for Occupational therapy. They conclude “most in-patient stroke units are operating below the DOH guidelines and are therefore challenged in providing the recommended amount of therapy and patient time to facilitate optimal functional recovery for stroke patients” (McHugh & Swain, 2014). It is estimated that due to other administrative duties which are non-patient contact time for therapists, a PwS on an acute stroke unit in the UK could receive as little as 5 hours of Physiotherapy during their stay (McHugh & Swain, 2014). It is also often reported that the upper limb is not given priority in the inpatient setting, as the focus is on transfers and mobility to facilitate discharge (The Stroke Association, 2012).

A study that observed the amount of movement practice provided during stroke rehabilitation, found that practice of task-specific functional upper limb movements occurred in 51% of sessions that addressed the upper limb. The average number of repetitions was 32, which is well below the number of repetitions that were found needed in animal studies to make cortical changes (Lang et al., 2009).

There is still little data available on the reality of care once a PwS has been discharged from hospital. A report by the Stroke Association found that almost half of people who have had a stroke had unmet needs for care and that over half wanted more information about stroke (McKevitt et al., 2010). A Care Quality Commission (CQC) report found therapy services were generally available but found wide levels of variation in the accessibility and quality of care and support provided to people after they have been transferred home (Care Quality Commission, 2011). Early supported

discharge teams are still evolving and not all patients meet the criteria for an Early Supported Discharge (ESD) team. Other rehabilitation services vary significantly in their provision across the country, with 32% of primary care trusts reporting that they did not commission specialist stroke physiotherapy in the community (Care Quality Commission, 2011).

The CQC report in 2011 also found while most Primary Care Trusts (PCT) had a system in place for reviewing treatment, around two thirds of the 6 week reviews were taking place, and 6 month reviews were planned in 44%, the actual number undertaken was not known (Care Quality Commission, 2011). While these standards exist it is unclear how this is communicated to the PwS and their family. For example, the CQC found that despite PCT's having policy of carrying out reviews, only one in ten of the information packs given to people around the time of their transfer home mentioned these reviews or set out their rights to ask for a reassessment if their needs change.

2.6 Perspective of People with Stroke

The literature review, up to this point has focused on objective measures of recovery of the upper limb and factors influencing these. However, factors other than the amount, and nature of therapy provided may also influence recovery. Further, in many, if not most, research studies, the primary outcome measure is concerned with impairment or ability to perform functional tasks, PwS may consider other factors to be equally, if not more important.

The concept of recovery from the PwS perspective is reviewed, along with factors such as attitudes and approaches, motivation, education and information and the influence of rehabilitation professionals in their interactions and attitudes with the PwS. There is also a perceived imbalance between the rehabilitation professionals focus on the physical impact of stroke and the PwS's perspective of not just their physical needs being met but their psychological, emotional and social needs. The section concludes with a review the impact of upper limb impairment on quality of

life and participation, and specific factors found to responsible for contributing to upper limb recovery.

2.6.1 Overview of factors influencing recovery following stroke: PwS perspective

A small number of papers have reported on PwS experiences and perceptions of rehabilitation and stroke recovery (Luker, Lynch, Bernhardsson, Bennett, & Bernhardt, 2015; Peoples, Satink, & Steultjens, 2011), while even fewer have specifically considered the upper limb.

Graven et al (2013) explored the concept of recovery from the perspective of PwS and their carers (Graven et al., 2013). The main theme that emerged was of ‘individual recovery expectations’, that recovery is an individual phenomenon, comprising of a broad range of factors extending beyond physical improvement alone (Graven et al., 2013). Recovery was considered to be a process of gradually returning to previously valued activities, and could be used as a benchmark of improvement for PwS. Themes of perseverance, keeping going and maintaining hope for improvement are common in the literature regarding PwS perceptions of important factors in recovery (Barker & Brauer, 2005; Graven et al., 2013).

MacLean et al (2000) noted that rehabilitation professionals have long held the belief that patient motivation affects outcome, but there is little research in the area (Maclean, Pound, Wolfe, & Rudd, 2000). In the data that emerged from semi-structured interviews, MacLean et al explored the attitudes and beliefs of 22 stroke in-patients, who were deemed as having high or low motivation by the rehabilitation professionals. They found PwS with high motivation were found to align themselves more closely to the aims and methods of rehabilitation professionals, and were more likely to understand the nature and purpose of their rehabilitation than those with low motivation. Factors that were found to be positive determinants of motivation were information about rehabilitation, favourable comparisons with other stroke patients and the desire to leave hospital (Maclean et al., 2000). Negative determinants of motivation were found to be lack of information, overprotection from family and

professionals and the provision of mixed messages about rehabilitation to patients from staff (Maclean et al., 2000).

2.6.2 The influence rehabilitation professionals have on the recovery of PwS

A number of studies have explored the influence of rehabilitation professionals' interactions and attitudes on the experience of PwS during recovery (Jones, Mandy, & Partridge, 2008; Luker et al., 2015; Maclean et al., 2000; Peoples et al., 2011). In a 2008 study, participants reported positive impacts of therapist interactions, including therapists assisting with their motivation and being encouraging, and viewing rehabilitation as a joint effort between them and the therapists (Jones et al., 2008). Peoples et al (2011) found participants reported negative interactions with staff, with dignity and respect being challenged, conversely, a kind, respectful and hopeful attitude was able to outshine the negative interactions and encouragement from therapists in rehabilitation sessions strongly influenced satisfaction (Peoples et al., 2011).

People with stroke can suddenly be dependent on all those around them, both in the hospital and at home, and this 'lack of control' over their daily lives was associated with fear, frustration and anxiety (Luker et al., 2015). In the light of this, a number of studies have found that participants felt a loss of autonomy in dealings with their therapists, potentially further reinforcing this perception of reduced control over their lives (Jones et al., 2008; Luker et al., 2015; Peoples et al., 2011). Some participants reported that feelings of improved levels of control were associated with recovery of functional abilities, suggesting a complex interaction between therapy, recovery and patient autonomy (Luker et al., 2015).

Information on stroke and recovery is a key factor highlighted across qualitative studies. Participants cited information from staff as essential to help them understand what had happened to them, the process of recovery and rehabilitation and the idea that they would not naturally get better, or that there would be a 'magic' solution (Maclean et al., 2000). In the same study, participants with low motivation reported anxieties that stemmed from a lack of information. Information was perceived to

support PwS as an active member of their rehabilitation, not a passive recipient (Luker et al., 2015; Peoples et al., 2011).

A review of PwS experiences of rehabilitation (Peoples et al., 2011), revealed a perceived imbalance in the focus of clinical staff compared to the PwS. The emphasis of clinical staff tended to be on the physical needs of the PwS, with little attention to their non-physical needs such as, social aspects, spirituality, couples counseling and psychological support (Graven et al., 2013; Peoples et al., 2011). Jones et al (2008) also discussed how the physical measures of recovery dominate and are not only the key focus for clinicians, but also tend to be prioritised in stroke research (Jones et al., 2008).

Barker et al (2007) conclude that PwS have a long term view of recovery and stroke services would benefit from a self-management and self-improvement approach that could prepare and guide PwS through the psychological, physical, emotional, social and educational aspects of recovery (Barker, Gill, & Brauer, 2007). Barker proposed that people with stroke should be equipped with the skills, knowledge and confidence to drive their own recovery (Barker et al., 2007), as in reality most PwS, once they are past the initial rehabilitation period, are out there on their own with no professional support.

2.7 Impact of Upper Limb Impairment Following Stroke

2.7.1 PwS perspective of factors associated with upper limb stroke recovery

Upper limb impairment can have wide ranging physical, social and psychological impacts. A study investigated the outcome of arm function four years after stroke and found many participants, even those with moderate to good Fugl-Meyer (FM) scores, still reported the loss of function in the arm to be a major problem (Broeks et al., 1999). Upper limb motor impairment is also associated with a low level of subjective well-being (Wyller, Sveen, Sodering, Pettersen, & Bautz-Holter, 1997). Poor upper limb functioning can negatively influence participation in functional and leisure activities (Sveen et al., 1999). Morris et al (2013) examined the role upper limb

dysfunction in predicting health related quality of life (HRQOL) six months after stroke (J. H. Morris, van Wijck, Joice, & Donaghy, 2013) and found upper limb impairment to be an important predictor of perceived physical HRQOL. Barker and colleagues (Barker & Brauer, 2005; Barker et al., 2007) investigated what upper limb deficits mean to PwS, their differing beliefs and behaviours with regard to upper limb recovery, and to determine what factors other than medical diagnosis and co-morbidities contribute to recovery of the upper limb after stroke in the chronic phase. Barker postulated that PwS who showed continued recovery after 6 months had either achieved the required amount and type of task practice to promote their recovery in terms of task specificity and progression to achieve their goals, or had employed equally effective strategies to promote recovery (Barker et al., 2007).

In the first stage of their work, Barker et al (2005) conducted focus groups and in-depth interviews which sought to identify from the PwS's perspective, factors contributing to upper limb recovery (Barker & Brauer, 2005). In the second stage Barker et al (2007) surveyed 220 participants with upper limb impairment who were more than 3-months post stroke (mean of 4.9 years post stroke) (Barker et al., 2007). The survey was developed using content sourced from existing instruments with demonstrated reliability and validity, together with some material taken from a previous study (Barker & Brauer, 2005). The survey, despite being long and potentially challenging for stroke participants to complete (at 8 pages with 96 items), was piloted and adequate test-retest reliability was established. The survey participants were found to be a representative sample of the stroke population in Queensland, Australia in age, gender and place of residence, but the results may not be representative of people with stroke in other countries. Findings from part of the survey, an upper limb self-reported recovery rating (measured by the recovery item of the Stroke Impact Scale) varied from 23% reporting no recovery at all, 70% reporting 50% or less recovery and less than 2% reporting full recovery (Barker et al., 2007). Certain factors were found to correlate with recovery. Positive correlations were found between self-reported recovery rating and 'hope for recovery', 'confidence to do what needs to be done', 'using the arm in everyday tasks', 'knowing how to improve', 'knowing where and how to get help' and 'helpful information from my own efforts'. Negative correlations were found between the same self-reported recovery rating and 'feeling I can't do things properly', 'lack of help from health

professionals' and 'not enough movement to work with' (Barker et al., 2007). A high proportion, 90% of participants reported being 'determined and persistent' and 83% reported 'getting help from family and friends'.

In terms of the relative contribution of these factors to recovery, 'use of the arm in everyday tasks' was responsible for more than 12% of the unique variance in recovery and was the single largest independent predictor of recovery (Barker et al., 2007). The second most significant factor was 'not enough movement to work with' which represented the greatest barrier to recovery reported by 52% of participants (Barker et al., 2007). Barker postulated that technologies such as FES and robotics should lead the way in providing sufficient practice for those PwS with severe paresis.

Barker et al found that those that perceived they had recovered well were more likely to have hope, confidence and a sense of responsibility for driving their own recovery. The extent of self-reported upper limb recovery can be dependent on the commitment of the individual, and this underlines the importance of the psychological aspect of recovery (Barker et al., 2007).

2.8 Functional Electrical Stimulation

2.8.1 Background

Neurons are cells, which transmit messages or impulses in the nervous system. A typical neuron has 3 parts, the cell body, dendrites and an axon (see Figure 2.1). When a motor nerve axon approaches a muscle that it innervates, it divides into multiple branches, each of which makes a synapse called a neuromuscular junction with an individual muscle fibre.

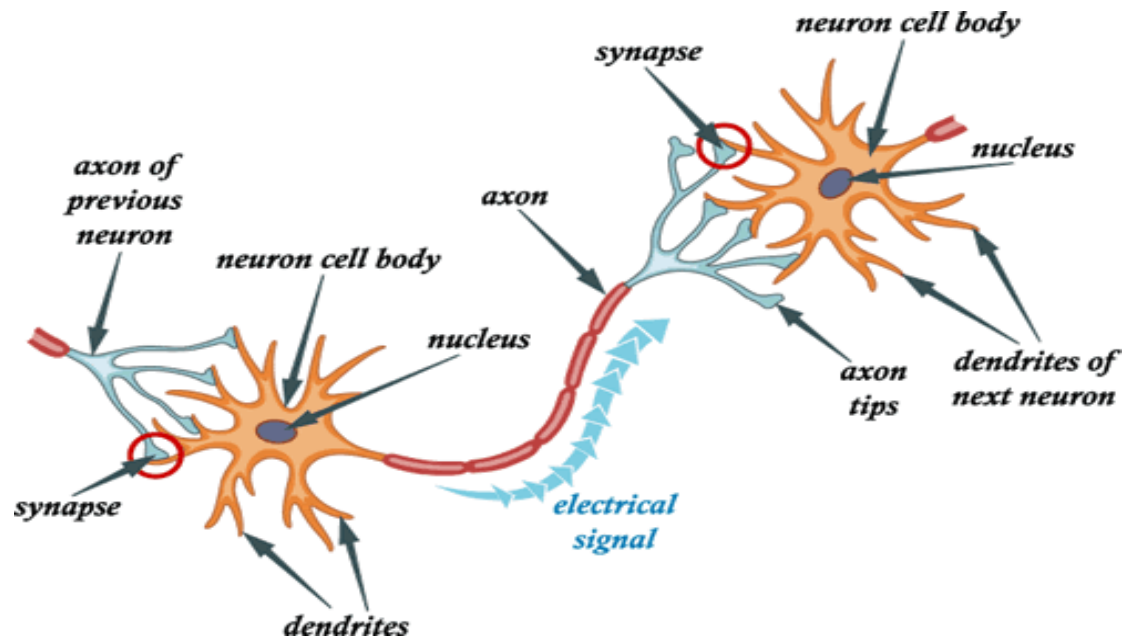


Figure 2.1 Neuron cell structure

At rest an axon internally has a negative electrical charge compared to the outside of the cell (-70mV), described as a resting potential. This is caused by a difference in the concentration of chemical ions between the inside and outside of the cell, with a high potassium (K^+) concentration, and low sodium (Na^+) on the inside and a high concentration of Na^+ and low K^+ on the outside in the extracellular fluid, with an electrical pump inside the cell membrane maintaining the concentrations (Shumway-Cook & Woollacott, 2001). When the axon is stimulated it momentarily reverses polarity to positive inside the cell then quickly reverts back to negative. The change in potential is from -70mV to $+30\text{mV}$, achieved by the opening up of the chemical channels allowing a rush of Na^+ into the cell causing the inside of the cell to momentarily be positive. Potassium channels then open causing a flood of K^+ ions out of the cell leaving it negatively charged again at its resting potential. This sudden change across the membranes of the cell is called an action potential or nerve impulse and propagates along the axon (Baker, Wederich, McNeal, Newsam, & Waters, 2000).

2.8.2 Electrical stimulation - definition

When an external electrical source is applied to a motor neuron, it alters the electrical field surrounding a nerve's axon, and if this field increases to a certain level action

potentials are induced. A depolarisation of the neuron membrane occurs near the cathode, as positive sodium ions are attracted by the negative electric field, reducing the positive charge on the outside of the membrane (Baker et al., 2000). Decreasing the positive ions outside the membrane, allows larger protein anions, which are found outside the cell with a negative charge, to drop into the cellular sink away from the membrane itself. This then reduces the potential difference across the cell membrane and raises it closer to the threshold for excitation. With a positive potential at the anode, the outside of the membrane is made even more positive than usual, there is an increased potential difference between inside and outside, which actually hyperpolarises the nerve membrane, compared to the normal physiological process (Baker et al., 2000).

When action potentials are generated with an external source, such as electrical stimulation, they travel in both directions from the site of excitation, both away from the cell body (orthodromic impulse), and towards the cell body (antidromic impulse) (Baker et al., 2000).

2.8.3 Functional Electrical Stimulation – definition and overview

Neuromuscular electrical stimulation (NMES) is the electrical stimulation of an intact lower motor neuron to activate paralysed or paretic muscles (Sheffler & Chae, 2007), Functional Electrical Stimulation (FES) is “the use of NMES to activate paralysed muscles in precise sequence and magnitude so as to directly accomplish functional tasks” (Sheffler & Chae, 2007). Current applications for FES include standing, walking, cycling, control of respiration and bladder function, but this thesis concentrates on its use in the upper limb to assist performance of functional tasks (Sheffler & Chae, 2007).

An FES system comprises a stimulator, associated electrodes, and one or more sensors. Surface electrodes, are most commonly used, which attach to the skin via a hydrogel pad. Electrodes can also be implanted and have been used in this way especially in the lower limb foot drop application of FES (Schiemanck et al., 2015), however this not yet common in upper limb applications.

2.8.4 Upper limb FES systems

In this section, the upper limb FES systems are reviewed. There are a number of reports of stimulation systems for the upper limb in research, although only one dedicated upper limb system is on the market, the H200 manufactured by Bioness Inc. The H200 wireless hand rehabilitation system consists of an orthosis (see Figure 2.2) and a wireless control unit. The orthosis supports the wrist in a functional position, the electrical stimulation is individually programmed to assist with reaching, grasping, opening, closing of the hand and pinching activities. Stimulation is triggered by user activation of the pre-programmed wireless control unit. It has the advantages of being wireless, quick to don and doff and individually programmed, however it only stimulates around the wrist, fingers and thumb and so caters to a specific level of impairment only.



Figure 2.2 Bioness H200 Neuroprosthesis

Knutson et al have developed contralaterally controlled functional electrical stimulation (CCFES) with a glove on the unaffected hand to trigger the stimulation (Knutson, Harley, Hisel, & Chae, 2007; Knutson et al., 2012; Knutson, Hisel, Harley, & Chae, 2009). Chan et al (2009) used a similar approach, a self-triggered accelerometer in a ring on the unaffected hand to produce hand opening on the affected side (Chan, Tong, & Chung, 2009). FES can also be EMG triggered where surface electrodes pick up the electromyography signal and stimulate the selected muscles in proportion to the integrated electromyography signal (Hara, Ogawa, & Muraoka, 2006).

Meadmore et al (2012) report on the feasibility of iterative learning control mediated by FES, whereby the controller adapts the amount of FES delivered based on previous attempts (Meadmore et al., 2012). This enables the participant to work at the limit of their ability supported by the FES to carry the tasks. This system also uses robotic support to carry out the tracking tasks. It is in the early phases of investigation but is promising technology aimed at supporting a participants voluntary effort (Meadmore et al., 2012). These systems have been reported in research papers but to the authors' knowledge do not exist commercially.

Despite the evidence for the importance of voluntary initiated task-specific practice, there is no commercially available system that enables the user to initiate movement and then be supported by the electrical stimulation to carry out a functional task. By using FES in this way, principles of motor learning of repetition, intrinsic feedback and sensorimotor integration can be exploited. Also most systems concentrate only on the wrist and fingers, and do not assist with shoulder flexion or elbow extension and the coordination and sequencing across these joints, which is required for more complex upper limb tasks and/or the more severely impaired patients.

The REAcH study uses the Odstock two channel programmable stimulator (O2PS) a CE marked device and is detailed in a paper by (Mann, Taylor, & Lane, 2011). The O2PS encompasses a biaxial accelerometer which detects movement of the arm as it attempts to reach forward, the accelerometer is within the device which is small enough to wear on the upper arm in a pouch see figure 2.3 below. The movement detected by the accelerometer is interpreted as a change of angle between the axis of the device and the earth's gravitational field, when this reaches a pre-set angle the device triggers the stimulation (Mann et al., 2011). The stimulation is delivered via two channels; one stimulates anterior deltoid and triceps assisting shoulder flexion and elbow extension respectively. The other channel stimulates forearm extensors to assist with wrist and finger flexion and opening of the hand for functional tasks. The device can also be set to deliver cyclic stimulation. Throughout the thesis it is referred to as the FES device.

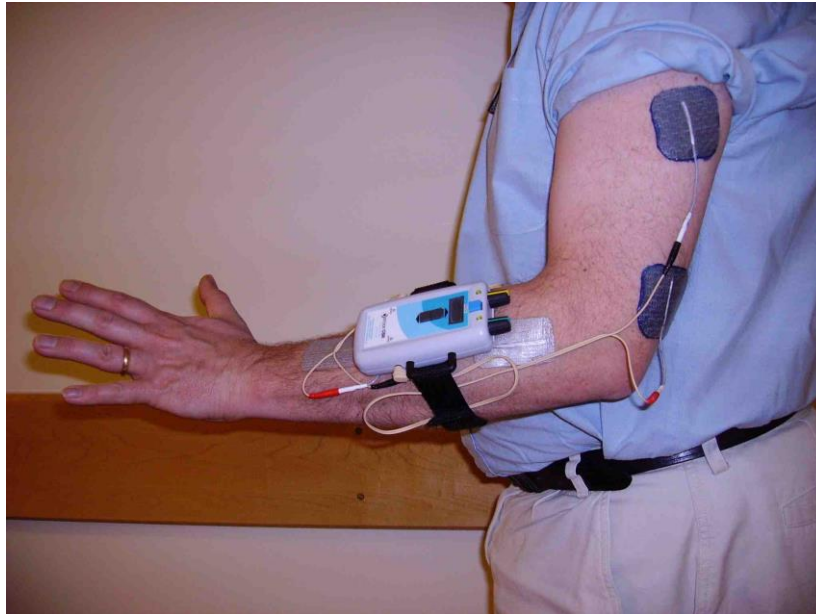


Figure 2.3 Odstock 2-channel programmable (O2PS) / REAcH stimulator

2.8.5 Theoretical basis for FES - Neuroplasticity and motor learning

Upper limb studies have found that combining voluntary effort with appropriately timed (via EMG or push button) electrical stimulation to lower motor neurons can lead to an increase in cortical excitability compared to electrical stimulation or repetitive voluntary training alone (Barsi, Popovic, Tarkka, Sinkjaer, & Grey, 2008; Bhatt et al., 2007). It is postulated the peripheral effect of electrical stimulation in changing somatosensory input and the centrally mediated mechanism of motor learning, are together more effective in producing changes in cortical excitability (Barsi et al., 2008; Bhatt et al., 2007). This effect has also been shown in lower limb studies (Khaslavskaja & Sinkjaer, 2005; Thompson, Doran, & Stein, 2006).

There may also be an effect of FES combined with voluntary activity at spinal level. Rushton hypothesised that the Hebb-type corticospinal-anterior horn cell synapses, may be open to modification by electrical stimulation (Rushton, 2003). Rushton proposed that electrical stimulation-induced activity may artificially synchronise presynaptic and postsynaptic activity in the affected anterior horn cell, and that this may strengthen these synaptic connections (a process often referred to as ‘neurons that fire together, wire together’).

2.8.6 Literature Search Methods

Searches for articles were made via the University of Salford's online resources, the databases used were Medline, Cinahl and Academic Search Premier. Search terms used included: functional electrical stimulation or electrical stimulation or neuromuscular electrical stimulation; upper limb or upper extremity or arm or paretic arm; stroke or hemiplegia or hemiplegic or paresis or hemiparesis or cerebrovascular accident. Search results revealed papers, which were screened on reading of the title and/or abstract for relevance to the study aims. Hand searching of papers and reference lists revealed further articles. Searches were repeated over the course of the study to check for recently published relevant articles.

2.8.7 Evidence for FES in acute stroke rehabilitation

A few studies have looked at PwS with a mild to moderate paresis in the acute stages, with others focusing on those more severely affected. An early study by Powell et al (1999) involving 60 participants (30 in an intervention group and 30 in a control group) (Powell, Pandyan, Granat, Cameron, & Stott, 1999). The treatment group were given stimulation to the wrist extensors 3 times a day for 30 minutes for 8 weeks. However, the ES was not used to support functional movement or task practice. Participants were followed up at the end of the 8-week intervention period and 24 weeks after the end of intervention. Significantly greater increases in isometric wrist extensor strength were seen at the end of intervention in the treatment group compared to the control, and these changes were maintained at follow up. A trend ($p=0.11$) towards better functional improvement in the treatment group compared with the control group was also seen in the total ARAT scores. The trend continued at the follow up measure of total ARAT scores, but differences between the groups were also not statistically significant.

A single-blinded study investigated the effects of functional electrical therapy (FET), consisting of an exercise program of voluntary arm movements opening, closing, holding and releasing of objects assisted by a neural prosthesis (electrical stimulation) (M. B. Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich, 2003). The FET group received 30 minutes a day for 3 weeks in addition to conventional therapy. The

control intervention was the same program of exercises, for the same duration daily without the electrical stimulation. The participants were divided into higher functioning groups (HFG) and lower functioning groups (LFG) for each intervention dependant on their ability to actively extend the wrist and fingers (M. B. Popovic et al., 2003). There were four groups in all, and with only 28 participants overall there was not more than 8 participants in any one group. However, the FET and control groups showed a recovery trend in all outcome measures, and gains were maintained at a 26 week follow up. The gains in FET groups were much larger compared with the gains in control groups. The LFG subjects showed less improvement than the HFG in both the FET and control groups. One explanation for this finding could be that LFG's found more difficulty performing the required functional tasks, even with the aid of stimulation, as the stimulation only assisted finger and thenar muscles and not more proximal muscles. For the LFG the average number of successful repetitions per session was 0 at the start for both the FET and control groups. Small increases in number of repetitions were seen in both groups. Despite larger increases in the number of repetitions in the HFG's, the average number of repetitions achieved were still low at the end of the intervention period (29.9 for the FET and 15.4 for the controls) in terms of promoting plasticity. A statistically significant decrease in muscle spasticity measures by the Ashworth scale was only seen in subjects in the HFG who had FET. This study also looked at the users' satisfaction with the Reduced Upper Extremity Motor Activity Log and both HFG's showed increased satisfaction at the end of the study, and there was a statistically significant difference between the groups in favour of the FET group. Satisfaction was lower in both the LFG's.

A later pilot study by Alon et al (2007) of 15 individuals, used a well-designed training program, comparing FES with tailored task specific therapy with task specific therapy alone, all participants regained hand function, with significantly better improvements in the FES group for all outcome measures (Alon, Levitt, & McCarthy, 2007). Following an informative but mainly descriptive review of FES applications, Popovic et al (2009) also suggested that repetitive, active movement mediated by electrical stimulation can enhance motor re-learning following damage to the CNS, and should be applied in the acute phase to increase effectiveness. He argued that application in the chronic phase requires prolonged and more intensive treatment to overcome secondary loss of function from disuse (D. B. Popovic, Sinkaer, & Popovic,

2009). Despite this being in line with theories related to learned non-use Popovic did not back up the conclusions with any detailed analysis of the studies described.

Any type of task practice can be very difficult to achieve in severely affected or completely paralysed PwS, without the use of a technology, such as FES (M. R. Popovic, Thrasher, Zivanovic, Takaki, & Hajek, 2005). There have been various studies looking at the use of FES in this stroke population. Popovic investigated 13 subjects with no active movement at baseline. After 12 to 16 weeks of training with FES and conventional therapy, compared with a control group who received conventional therapy, all subjects in the FES group had active movement and were able to use their upper limb in activities of daily living (ADLs). The majority of the control participants did not improve their arm and hand functions significantly and were not able to use them in ADLs (M. R. Popovic et al., 2005).

Alon et al (2008) compared FES plus task specific training to task-specific training alone in 26 severely affected acute stroke subjects (Alon, Levitt, & McCarthy, 2008). The study found, despite the small numbers and high dropout rate, the FES plus training group showed improved outcomes compared to the task specific training group alone. The H200 neuroprosthesis was used, which stimulates the wrist and finger extensors only in timed delivery of stimulation, and in severely impaired PwS no consideration was given to the function and stability of the elbow, shoulder or shoulder girdle, an issue raised by Mann et al (2005) previously (Mann, Burridge, Malone, & Strike, 2005). Compliance data was also lacking, making dose effect conclusions difficult. Interestingly, after 12 weeks training a plateau was not seen in functional improvements, however longer term follow-up measures were not carried out.

FES was found to be not superior to conventional therapy in a study of 23 acute participants with severe or complete paralysis (Mangold, Schuster, Keller, Zimmermann-Schlatter, & Ettlin, 2009). Group imbalances and small numbers weakened the validity of the intergroup comparisons. This study also explored the users' perspective and this highlighted an issue found in lower limb FES, as in a 45-minute therapy session 15-20 minutes were spent donning and doffing the FES, highlighting the need for user-friendly systems. Thrasher et al (2008) found

statistically significant improvements when FES was combined with conventional therapy, compared to conventional therapy alone (Thrasher, Zivanovic, McIlroy, & Popovic, 2008). In a small blinded study of 21 subjects' improvements were seen in object manipulation, palmar grip torque, pinch grip and an array of other outcome measures.

Despite small sample sizes and methodological difficulties, the results suggest FES, when combined with conventional therapy and/or task specific training may be effective in reducing motor impairment and increasing function. A few studies have included a follow up period to further assess the intervention and this is discussed in section 2.8.8. Only Popovic et al (2003) who looked also at satisfaction, took any account of the users' perspective on the intervention (M. B. Popovic et al., 2003). Authors agree FES can assist those with a more severe impairment often referred to quoting Barkers 2005 paper as "not enough to work with" (Barker & Brauer, 2005). FES can act as "bridge" for this group who otherwise would not be able to participate in repetitive task practice (Hayward, Barker, & Brauer, 2010; Howlett, Lannin, Ada, & McKinstry, 2015; Page, Harnish, Lamy, Eliassen, & Szaflarski, 2010).

2.8.8 Evidence for FES in chronic stroke rehabilitation

Early studies focused on cyclic or exercise electrical stimulation, where stimulation is pre-programmed in a timed on/off sequence with no active user control. Systems often provided stimulation to just one muscle group or joint. Positive effects were reported, for example, with an increased range of wrist motion (Pandyan, Granat, & Stott, 1997). However, as noted previously, further evidence suggested the need for repetition of functional, meaningful tasks to promote positive neural and functional changes. Cyclic stimulation paradigms can be limited in the opportunities for motor cortical plasticity to occur due to the lack of active user involvement and opportunity to engage in functional tasks or learn motor skills. Research therefore began to focus upon the study of increased user involvement with task specific practice and user triggered devices with the aim of promoting positive cortical remodelling.

Task practice combined with electrical stimulation was studied in 8 participants (Page et al., 2010) using a neuroprosthesis, the Bioness H200 to enable performance of valued activities in the home for 30-minute sessions every weekday for 8 weeks. Increases were seen in ARAT and FM scores and although active user intent was not required to initiate stimulation high field functional magnetic resonance imaging revealed significant increases in cortical activation (Page et al., 2010). Active user intent is required by electromyography (EMG)-triggered FES, although only in the initiation of the muscle contraction. Two studies compared cyclic stimulation with EMG-triggered stimulation and found no statistically significant differences between the treatment groups in either study (de Kroon & Ijzerman, 2008; Hemmen & Seelen, 2007). De Kroon postulated that the two types of stimulation are not distinct enough from each other to show differences due to the small amount of cognitive effort required in EMG-triggering (de Kroon & Ijzerman, 2008). Triggering may also be initiated via detection of movement in the contra-lateral limb via a ring or glove (Chan et al., 2009; Knutson et al., 2012). Knutson et al (2012) report an improvement in several upper limb measures with contralaterally controlled FES (CCFES) via a glove on the unaffected hand, when compared to a control group receiving cyclic stimulation (Knutson et al., 2012). Chan et al (2009) compared self-triggered FES with placebo stimulation, both groups participating in bilateral upper limb training (Chan et al., 2009). The participants used a self-triggering mechanism with an accelerometer as a motion detector placed in a plastic ring worn on the unaffected index finger. Statistically significant changes were seen in impairment and function measures compared to the control group.

The O2PS was developed in response to the need to develop electrical stimulation systems with active user involvement and to facilitate task practice (Mann et al., 2011). The O2PS device uses an accelerometer to control stimulation where the trigger is generated by the user initiating a forward reach to grasp movement with their impaired limb, thus providing stimulation which can be triggered ‘on demand’ to facilitate task practice.

The 2012 Evidence Based Review of Stroke Rehabilitation (EBRSR) felt the weight of evidence was in favour of FES being a beneficial treatment in chronic stroke (Foley, Teasell, Jutai, Bhogal, & Kruger, 2012). However the evidence supporting use

of FES in this setting is variable and several reviews, including a recent Cochrane review, have failed to demonstrate robust evidence to support upper limb FES (Howlett et al., 2015; Pollock et al., 2014; Quandt & Hummel, 2014; Vafadar, Cote, & Archambault, 2015). Conversely, a recent meta-analysis reported FES was associated with a large positive effect on upper limb activity compared with the control group (Howlett et al., 2015). It is noted that study protocols can be highly heterogeneous, especially with regard to dosage and timing of treatment, making comparison of results difficult (Quandt & Hummel, 2014) and in addition there is a lack of available data to determine if participation is improved or if the benefits on activity are persistent.

In summary FES is a promising technology in the acute and chronic stroke populations. It enables PwS to participate in task specific practice, bimanual and bilateral tasks and be an active participant in their rehabilitation. It can also allow some patients with a more severe impairment to be able to participate in repetitive task practice. However further research is needed, as interventions, dosages are heterogeneous, study numbers tend to be low and studies lack long term follow up to fully assess the persistence of any effect. The majority of studies also lack information from the users' perspective on the reliability and usability of the device, as well as qualitative data on the trial protocols, and participants' views on their upper limb recovery process.

2.8.9 Long-term follow-up in upper limb FES studies

A refinement of the search strategy outlined in 2.8.6 to identify only those studies with long term follow was attempted. However, despite refinement of the search terms, the search strategy did not identify the set of relevant papers already known to the researcher. Therefore, hand searching of the set of papers identified using the strategy outlined in 2.8.6 was used to identify upper limb FES studies in stroke with long term follow up. Studies were excluded from this list if the intervention was invasive, or used sensory stimulation only. The set of 13 relevant papers are shown in Appendix 1. These followed up participants for between two and nine months' post-intervention. Participant numbers tend to be low, ranging from 9 to 66 (with a mean of

27) as also seen in a significant proportion of FES studies above. The studies cover a range of time points post stroke from acute to chronic participants, and across the spectrum of severity of paresis from mild to severe. The type and dose of electrical stimulation delivered also varies significantly across these studies making comparison difficult. A number of different outcome measures are also used, although ARAT and the WMFT were commonly used for function and Fugl-Meyer for impairment. Many studies focus only on the wrist and/or hand (Knutson et al., 2012; Kowalczewski, Gritsenko, Ashworth, Ellaway, & Prochazka, 2007; Kraft et al., 1992; Persch, Page, & Murray, 2012; M. B. Popovic et al., 2003; Powell et al., 1999; Tarkka, Pitkanen, Popovic, Vanninen, & Kononen, 2011). Only a minority include stimulation of the shoulder and / or elbow (Z. Lin & Yan, 2011; Mann et al., 2005; Mann et al., 2011).

Maintenance of any intervention related improvement in measures was variable across these studies. A significant early study found that chronic PwS could achieve and maintain improvements 9-months post intervention of EMG-triggered electrical stimulation (Kraft et al., 1992). In a later study, significant improvements were seen between electrical stimulation and control groups in the grasp and grip subsections in the ARAT scores at the end of intervention. These differences were no longer significant at a 24 week follow up (Powell et al., 1999). A subsequent study with a similar intervention found no significant differences between groups following a 6-week intervention of NMES, or at the follow up at 36 weeks (Rosewilliam, Malhotra, Roffe, Jones, & Pandyan, 2012). Contra-laterally controlled FES was associated with improvements in several measures maintained at 3 months (Knutson et al., 2012), however Kowalczewski et al (2007) used a push button system controlled with the contralateral hand (Kowalczewski et al., 2007) and reported improvements in WMFT at 3 months which had been lost by 6-months follow-up. Lin and Yan (2011) found significant improvements in both a cyclic FES group and a control group receiving conventional therapy, both for 30 minutes a day, 5 days a week for 3 weeks (Z. Lin & Yan, 2011). Both groups saw improvements in Fugl-Meyer Assessment (FM) and Modified Ashworth Scale (MAS) at the end of intervention and that persisted at 6 months, with the scores at 6-months significantly better in the FES group.

As noted above, comparison of FES studies is difficult due the heterogeneity of the studies in terms of intervention details (equipment and dose) as well as outcome

measures. However, there is more consistency in the literature in study design, with very few studies including follow up to evaluate the long term effects of the intervention being reported. No studies explored follow up over longer than 9 months. Also, there are very few studies which evaluate the intervention from the perspective of the user. This is somewhat surprising, given the importance placed by the users on recovery factors other than purely physical, as well as the usability issues, which inevitably arise with use of complex upper limb FES systems.

The only study to date that have combined task practice, with voluntary movement controlled multi-joint stimulation is the pilot that led to the REAcH study (Mann et al., 2005; Mann et al., 2011) which included a three month follow up period, at which point gains made were maintained. This study also addressed some aspects from the users' perspective through the use of the Canadian Occupational Performance Measure (COPM), the Psychological Impact of Devices Scale (PIADS) and the Use of Device Questionnaire (UDQ), as well as the use of diaries. The study is discussed further in section 2.9.

2.9 Odstock 2 Channel Movement-Triggered Pilot Study and REACH Study

The pilot, to the REAcH study was a longitudinal case series design and recruited 15 volunteers who had at least 45 degree's shoulder flexion and could initiate elbow extension and grasp (Mann et al., 2011). An initial baseline period of 4 weeks was followed by 2 weeks of exercise stimulation carried out at home without using the triggering function, to become accustomed to the device. Participants were then taught how to use the triggered stimulation, and practiced 4 functional tasks at home using triggered stimulation for 2 sessions of 30 minutes a day, then used the system daily to assist them in their ADL over a period of 10 weeks. Stimulation was via two channels, one to elicit elbow extension, the second channel to elicit wrist and finger extension (see section 2.7.4 Upper limb systems). Assessments were conducted at the beginning and end of baseline (weeks -4 and 0), weeks 2, 6 and 12 (end of intervention) and at week 24 (12 weeks after treatment was withdrawn).

Between week 2 and week 12 (period of triggered stimulation) the median Action Research Arm Test (ARAT) score improved from 19 to 32 ($P = 0.002$); the Modified Ashworth Scale (MAS) score for elbow, wrist, and finger flexor spasticity was reduced from 2 at each joint to 1, 0, and 1 respectively ($P = < 0.05$). The Canadian Occupational Performance Measure (COPM) performance and satisfaction scores improved ($P = 0.001$) and the Psychosocial Impact of Assistive Devices Scale (PIADS) became positive for competence ($P = 0.005$), adaptability ($P = 0.008$), and self-esteem ($P = 0.008$). Crucially gains were maintained at 3-month follow-up (week 24), median ARAT scores increased to 33 ($P = 0.001$) and all but two participants reported their hand function had improved when they were not wearing the device. MAS scores demonstrated a reduction in resistance to passive movement, that was maintained at follow-up. The changes in COPM scores were also maintained at follow-up with median performance score rising to 3.6 ($P = 0.03$) and satisfaction score to 3.8 ($P = 0.01$). The PIADS was not repeated at week 24. The Use of Devices Questionnaire (UDQ) results revealed the time spend using the device each day was between 1 and 12 hours with a mean of 3 hours a day, shared between triggered practice, their chosen COPM tasks and practice of any other ADL they wished to attempt. Participants reported changes as a result of using the stimulation. All participants reported increased awareness of the hemiplegic arm, 5 reported reduced muscles stiffness, 12 increased movement, 1 increased sensation and 1 reduced discomfort at the elbow. Generally, there was positive feedback on usability and functionality, although there were some reports that the triggering lacked sensitivity.

Following the successful pilot study (Mann et al., 2011), funding for a randomised controlled trial was obtained. The aim of the REACH RCT was to evaluate the effectiveness of a 2-channel, movement triggered upper limb stimulation system with a chronic stroke population.

The REACH RCT, differed slightly to the pilot's protocol (Mann et al., 2011) (See Appendix 2 for the full details of the REACH study). The study was conducted at two sites (Salisbury and Salford), included a control group and the baseline period was six weeks not four. In REACH all assessments without the device were blinded (non-blinded in the pilot), and triceps stimulation was combined with anterior deltoid (triceps only in the pilot) to assist with shoulder flexion. Also the stimulator was set

up by a physiotherapist not an engineer, and crucially some reengineering of the stimulator design took place between the two studies. The inclusion criteria were the same. The FES group used the device on exercise mode for 2 weeks, as per the pilot, followed by 10 weeks of triggered stimulation and task specific practice within the home, together with set exercises. The exercise group practised set exercises and task specific practice. The intervention period was 12 weeks for both groups.

Fifty-nine participants were recruited to the study and forty-four completed the protocol. In the main outcome measure ARAT, the exercise group showed a statistically significant, but small increase at week 12 (mean change of 2.3, $P = 0.01$), which was maintained at week 24 (3 month follow up), but the median was below the MICD. No significant difference was seen in the FES group, and there was no significant difference in the change in ARAT scores between the groups, and no training effect was seen. Both groups increased their total FM score indicating an overall reduction in impairment level, the MICD however was only exceeded by the exercise group at week 24. There were no significant differences between groups. This pattern of small improvements in both groups, but no between group differences, was seen across all the outcome measures, but changes in the FES group were noticeably lower than those seen in the pilot.

The reason for the unexpectedly low improvements seen in the FES group compared with the pilot study, are discussed below. There were a number of usability, and reliability issues with the re-engineered FES device. For example, nine participants reported the device was difficult to put on, thirteen participants reported difficulty correctly positioning the device and the electrodes. In terms of reliability, a third of the participants reported device failure, for three of which this was a frequent occurrence, and nine reported the system delivering stimulation when they did not expect it. The device was reported to have been used for a median of 85 minutes a day, significantly less than in the pilot. Further, blinded assessment of outcome measures may also have contributed to the differences in outcomes seen in the participants who used FES between the pilot and REACH studies.

The author gave a presentation of the REAcH study at the 5th conference of the International Functional Electrical Stimulation Society (IFESS) UK and Ireland chapter in May 2015. A copy of the presentation can be found in Appendix 2.

2.10 Chapter Summary

Whilst there has been a great volume of evidence published in relation to FES in chronic stroke, studies suffer from being highly heterogeneous in terms of dosage, timing and type of intervention. The evidence base supporting the role of FES in motor relearning and neuroplasticity is also developing. However, in the UK, PwS are struggling to receive the minimum duration of therapy advised in national guidance, let alone doses in line with research from animal studies. Technologies such as FES may therefore play a role in assisting therapists to increase the amount of time in active therapy and practice out of therapy. FES may also be helpful in ‘bridging the gap’ for PwS who initially have severe impairment to be able to access other interventions, such as CIMT (Page et al., 2010).

There is paucity of evidence regarding the maintenance of any treatment effect seen in FES studies, as long term follow-up is lacking, making full evaluation of interventions difficult. In studies of other interventions, notably the EXCITE trial, investigating the effects of a 2 week intervention of CIMT, retention of improvement in functional use was seen up to 2 years after the intervention (Wolf et al., 2006; Wolf et al., 2008). This lends weight to the need to investigate the possible persistent effects of interventions beyond cessation of treatment, which could contribute to the cost effectiveness, planning and delivery of services in the future

The study was initiated, based on the promising results of the pilot study of the FES device, and in light of the authors’ highlighted need for a longer follow up period (Mann et al., 2011). The second part of this study aimed to look beyond maintenance of treatment effect, and sought to explore whether the results of the 12 month follow up can be predicted from pre-treatment and/or post-treatment level of function using ARAT as a primary measure. Mann et al (2005) found both lower and higher functioning subjects improved to the same extent based on initial scores. However,

various studies indicate those with higher functioning showed greater improvement than those with lower levels of function at the beginning of the study (Boyaci et al., 2013; Mann et al., 2005; M. R. Popovic, Popovic, & Keller, 2002; Powell et al., 1999; Sonde, Gip, Fernaeus, Nilsson, & Viitanen, 1998). Recent work, notably a re-analysis of the EXCITE trial (Schweighofer et al., 2009) suggests that once a person reaches his/her functional threshold, recovery of arm function can be maintained for periods of up to 1 year without additional therapy input, as a result of an increase in spontaneous use of the affected arm. Findings from the re-analysis of the EXCITE data found that for an average patient if function was high one week after therapy, use increased in the months following, however if the function was low use worsened, therefore the level of functional ability could predict change in use in the long term following therapy.

Stroke is a life-changing event, for those with residual impairment in their upper limb it can affect their quality of life. Despite the ability to predict recovery of the upper limb for some PwS, based on initial severity and physical abilities, predictive models do not take account of the multi-dimensional nature of the impact of stroke and the challenges faced. The perspective of PwS as they face these challenges, particularly in the chronic phase, is an under-researched area. The PwS perspective is not just a physical one, and unsurprisingly, psychological, emotional and social factors are also significant issues for them. There is a paucity of evidence related to the PwS's perspective, especially related to therapy interventions such as FES. This evidence could serve to strengthen the development, design and adoption of technologies such as FES, and give greater insight into the experience of recovery for a PwS in the chronic phase. The third part of this study therefore aimed to use qualitative methods to explore the overall experiences of the participants' upper limb recovery with specific attention paid to their involvement in the REAcH study and in the follow up period, to allow for more informed interpretation of the quantitative findings.

2.11 Thesis Aims

The aims of this thesis were to:

- To evaluate the long-term outcomes (12 months) of voluntary-triggered FES and individual exercises for the upper limb, following the removal of the interventions, with participants who have taken part in the REAcH randomised control trial
- To investigate how much of the variance in functional outcome at 12 months can be explained by the nature of the intervention and changes in function over the course of the REAcH study
- To use qualitative methods to explore the overall experiences of the participant's upper limb post stroke recovery, specifically during the REAcH study and the 12-month follow-up period of this study

Based on these aims a number of detailed objectives were identified:

- To capture changes in function, impairment and quality of life at 12 months post intervention
- To capture any upper limb-related changes perceived by participants to have occurred during REACH and the follow-up period
- To explore participants' perceptions and experiences of FES within the REAcH study and, where relevant, in the follow-up period
- To explore participants' views of facilitators and barriers to upper limb stroke recovery
- To explore strategies used by participants to further their own post stroke upper limb recovery.
- To further explore some of the participants' reported experiences and perceptions in the context of the quantitative results

Chapter 3 Quantitative Method

3.1 Introduction / Overview

This chapter describes the method of the study undertaken in this thesis. The chapter sets out the protocol and includes detail on recruitment, consent, ethical considerations and the outcome measures used.

3.2 Study Protocol

3.2.1 Study design

There are two parts to this mixed methods study. The design of the quantitative component of the study was a 12-month follow up to a randomized control trial. The design of the qualitative part of the study will be discussed in chapter 4.

The data collection for both parts of this study took place over 18 months, reflecting the spread of dates over which participants who later went on to participate in the MPhil (follow-up) study were recruited to the REAcH study. Figure 3.1 shows the timelines for the REAcH and follow up studies.

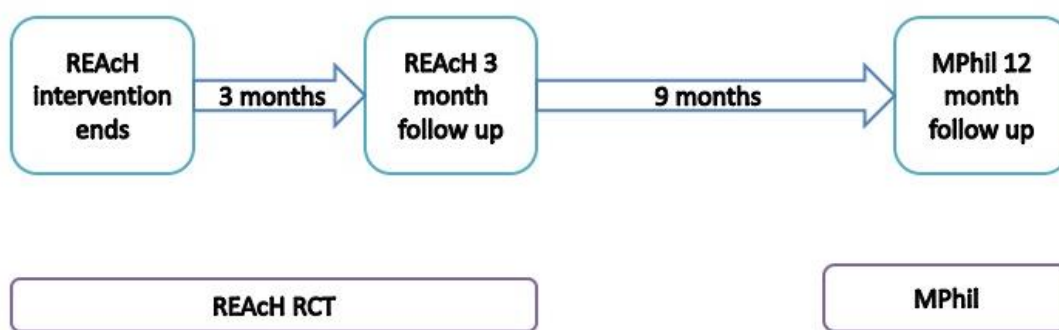


Figure 3.1 The REAcH and follow-up studies

3.2.2 Size of the study

The participants for this study were limited by the numbers of participants recruited to the REAcH study. The sample size for REAcH study of 60 was derived from a power calculation, based on the pilot study results (Mann et al., 2011). This study aimed to recruit the participants in the Salford arm of the REAcH study. Practical constraints prevented the researcher from following up participants in the Salisbury arm of the study.

At the time the protocol was written there was potential to recruit up to 30 participants to the follow up study (target number), as recruitment was split between the two sites. However, of the 28 participants were recruited to the Salford arm of the REAcH study, there were 7 dropouts and 1 incomplete data set, which left 20 potential participants to be recruited for this study.

The potential sample size of 20 participants was in line with other FES studies which included follow up (see appendix 1), in which the sample size ranged from 9 to 28 participants. From a qualitative aspect, the potential sample of 20 participants was in line with other related qualitative research. For example, in a synthesis of qualitative studies of the views of people post stroke, of the studies using interviews the average number of participants was 17.5, and for studies which used a phenomenological approach the average was 9 participants (Satink et al., 2013).

3.2.3 Selection criteria

Inclusion criteria

- To have completed the REAcH study at the University of Salford site
- Able to give informed consent
- Able to comply with study procedure
- Medically stable

Exclusion criteria

- New neurological, orthopaedic or other medical condition which has significantly affected their function of their paretic upper limb, or rendered them unable to take part in the study.

3.2.4 Recruitment

Ethical approval from the University of Salford was sought prior to the commencement of the research. Following ethical approval (Appendix 3) volunteers who had completed the REAcH study at the University of Salford site were invited to participate in this study. Potential participants were contacted via post with an invitation letter and accompanying information sheet (Appendix 4) inviting them to participate. It was stressed to the individuals in the information letter that they were under no obligation to take part in this study and that it was a separate study from the REAcH RCT.

Individuals were contacted in this way approximately 1-3 months prior to the 12 month follow up point. They were asked to contact the researcher, either by phone or email, if they wished to find out more, ask any questions, and/or volunteer for the study. An amendment was approved by the University of Salford Research Ethics Panel in June 2012. The amendment allowed potential volunteers who had not responded within 2 weeks of the invitation being sent out, to be contacted once by telephone to clarify whether or not he/she would like to participate. If the participant declined, no further contact was made. This amendment was requested to address recruitment in light of the lower than anticipated number of participants from the Salford arm of the REAcH study.

3.2.5 Consent

If the participant chose to make contact with the researcher, or the researcher contacted the potential participant and they wished to proceed, then the inclusion and exclusion criteria were checked. If criteria were met, the potential participant was invited to attend an appointment at the University to continue the consent process and

proceed with the protocol. The protocol involved a single visit to the University of Salford, outcome measures were recorded and a semi-structured interview conducted.

On arrival for the appointment the researcher checked the participant had had time to read and consider the information sheet and checked the participants understanding of the study. The participants were given an opportunity to discuss the study and ask any questions. If the potential participant wished to proceed, they were then asked to sign two consent forms, one to be held by the researcher and one for the participant's records (Appendix 5). The participants were not coerced in any way during recruitment or in the study, and participants were free to withdraw from the study at any time without need to give a reason, as stated in the information sheet.

3.2.6 Safety

The study complied with local health and safety procedure at the University, and a risk assessment was in place for the study. No adverse events were recorded.

3.2.7 Bias protection

The researcher, who was a blinded assessor on the REAcH study, carried out the outcome measures and interviews. Inter- assessor reliability studies of the outcome measures had been made as part of the REAcH study.

Outcome measures were completed first, at which point the assessor was still blinded to the treatment group allocation of the subject within the REAcH study. The semi-structured interview followed, during which the group allocation of the individuals was to become apparent, hence at this point the researcher was considered unblinded to the group allocation. More relevant to the interviews was the fact that the interviewer knew the interviewees from the REAcH study, and the potential social desirability bias this introduced is discussed in section 4.7.3.

3.2.8 Appointment details

Appointments were arranged at a convenient date and time to the participant. This appointment lasted around 1.5 to 2 hours, depending on the length of the interviews. The data collection was video recorded as in the REAcH study (providing the participant had consented to this). The purpose of the video was to permit review of results and potentially for use at presentations such as conferences and feedback events.

3.3 Outcome measures

One of the aims of the study was to evaluate the 12-month outcome of voluntary-triggered FES and individual exercises for the upper limb, following the removal of the interventions, with participants who had taken part in the REAcH randomised control trial. This required the same measures to be taken at the end of the intervention and then at the end of the follow up period. All recruited participants were re-assessed using the same outcome measures as used in the REAcH study, xxx thereby reducing the additional burden on participants to a single visit.

One of the objectives of the study was to capture changes in function, impairment and quality of life at 12 months post intervention. Function was measured using the Action Research Arm Test (ARAT) (Van der Lee et al., 2001), which was used in both the pilot and REAcH studies and is a common upper limb measure of function in other FES studies (see Appendix 1). The Box and Block test (Mathiowetz, Volland, Kashman, & Weber, 1985) was also used in REAcH as a more objective, if limited in scope, functional test. Consistent with both the pilot study of REAcH, and REAcH, impairment was measured using the Fugl-Meyer Assessment (FM) (Gladstone, Danells, & Black, 2002) an internationally established measure, frequently used measure of impairment. The Modified Ashworth Scale (Bohannon & Smith, 1987) measuring spasticity was used in REAcH and was also measured in this study. It is not directly a measure of function or impairment, but influences them both. Quality of life was measured using the Stroke Impact Scale (SIS) (Duncan et al., 1999), which is a condition-specific measure designed to capture the impact of stroke on a broad range

of areas that influence quality of life. The Canadian Occupational Performance Measure (COPM) (Law et al., 1990) identifies patient-specific problems not captured by standard measures. The measures were carried out in the same sequence for each participant, as they appear below. Finally, a semi-structured interview was carried out, as this forms the qualitative part of the study details are found in chapter 4. The measures, including details on validity and reliability are briefly described below, and appear in the order in which they were taken in the study:

Stroke Impact Scale (SIS) – A self-reported health status measure of the impact of stroke on quality of life (Duncan et al., 1999). It is designed to assess multi-dimensional stroke outcomes. Version 3.0 was used and includes 59 items, assessing 8 domains: strength; hand function; ADL; Mobility; communication; emotion; memory and thinking and participation/ role function. An extra question about stroke recovery asks the PwS to rate on a scale of 0 -100 how much they feel they have recovered from their stroke. Excellent internal consistency has been reported for the SIS (Edwards & O'Connell, 2003). Test-retest reliability ranged from adequate to excellent (ICC = 0.7 to 0.92), with the exception of the emotion domain (ICC = 0.57) (Duncan et al., 1999). Good criterion validity has been found across each of the domain scales of the SIS, with discriminant validity being excellent (Duncan et al., 1999).

Modified Ashworth Scale (MAS) – Measures elbow, wrist and finger spasticity (Bohannon & Smith, 1987). It uses a 6-point scale, where 0 represents normal muscle tone and higher scores represent increasing levels of spasticity/resistance to passive movement. Although it is the most common clinical measure for spasticity, evidence related to reliability in chronic stroke is sparse. The inter-rater reliability for wrist flexors was found to be excellent, where the time since stroke was not reported (Bohannon & Smith, 1987). Excellent intra-rater reliability has been found in acute stroke (Gregson et al., 2000) and the same study found excellent inter-rater reliability for the elbow and wrist. The validity of the MAS is an under researched area; one study considered concurrent validity, and found a poor correlation between MAS and surface electromyography. No studies have examined the predictive validity of the MAS.

Fugl-Meyer Assessment (FM) – A common measure of impairment for both the upper and lower limbs (Gladstone et al., 2002), although only the upper limb assessment was used in this study. Joint range and pain are assessed and scored out of 24. The motor domain includes items assessing movement, coordination and reflex action of the shoulder, elbow, wrist and hand, each of which is scored on a scale of 0-2: 0 none; 1 partial completion; 2 full completion and is scored out of 66. The items are intended to assess motor recovery and do not incorporate functional tasks. Lin et al (2009), in a study comparing psychometric properties of several measures, found close correlation between FM and level of disability by ARAT score. The test-retest agreement of the FM was very high, with an intra-class correlation coefficient (ICC) of 0.99, and, when used by trained raters, was reliable in monitoring changes (J. H. Lin et al., 2009). Interrater reliability was also very high with an ICC of 0.96 (J. H. Lin et al., 2009). Results suggested that the FM is more discriminative than an alternative measure of impairment, the Stroke Rehabilitation Assessment of Movement measure, for PwS with very high or very low impairment.

Action Research Arm Test (ARAT) – A functional measure, aimed at assessing specific changes in upper limb function (Van der Lee et al., 2001). It requires the participant to handle objects of differing size, weight and shape. The ARAT consists of 19 items grouped into four subscales: grasp, grip, pinch and gross movement. Each subscale constitutes a hierarchical scale and all items are ordered according to ascending difficulty. The most difficult tasks are attempted first. Scoring is as follows: 0 unable to achieve; 1 partially able to achieve; 2 able to achieve but with abnormal patterns of movement or slower than normal; 3 able to achieve normally. The maximum possible score is 57. High intra- and interrater reliability of ARAT has been demonstrated in the chronic stroke population, with both ICC higher than 0.98 (Van der Lee et al., 2001). Lin et al (2009), has more recently reviewed and extended this work to find sufficient validity (concurrent and predictive validity) in a recovering cohort spanning acute and chronic phases (J. H. Lin et al., 2009). The ARAT was also found to have satisfactory minimal detectable change, supporting its use in clinical settings (J. H. Lin et al., 2009; Van der Lee et al., 2001).

Box and Block test (B&B) – A timed measure of unilateral gross dexterity (Mathiowetz et al., 1985). The test consists of a wooden box, divided into two

compartments by a partition and 150 2.5 centimetre cubed blocks. The participant is asked to move the blocks one by one from one compartment to the other. The score is the maximum score is the number of blocks that can be moved from one compartment to the other in 60 seconds. Very high inter-rater and test-retest reliability ($ICC > 0.95$) was found for the B&B in stroke patients (Platz et al., 2005). In terms of validity, a study comparing 5 upper limb tests, the B&B was the best predictor of upper limb function at 5 months post stroke (Higgins, Mayo, Desrosiers, Salbach, & Ahmed, 2005).

Canadian Occupational Performance Measure – Measures participants' perception of their performance of a task and their level of satisfaction with that performance (Law et al., 1990). Participants choose 10 ADL tasks they wish to improve and rate them in order of importance on a scale of 1 to 10. The five highest scoring activities are selected and used over the time course of the measure. At each time point of the measure, the participant is asked to rate each of the five tasks from 1 to 10 for both their performance of the task and their satisfaction with this. Test-retest reliability was found to be moderate for the item pool, which, unlike some of the measures discussed above, is not fixed, and good for the performance and satisfaction scores. Discriminant validity has been confirmed by comparing the COPM with five standardised functional measures (Cup, Scholte op Reimer, Thijssen, & van Kuyk-Minis, 2003).

3.4 Statistical Analysis

As the results of the REAcH study showed no between-group differences in any measures it was decided to look at the follow up cohort as one group. A Shapiro-Wilk Normality Test for normality was performed on the baseline data.

If data were normally distributed a paired t-test between data collected at week 0 and week 12 were used to identify whether or not any changes were evident in the group over the intervention period. In cases where changes were seen, a further paired t-test was applied between data collected at week 12 and week 64 to test whether these

changes were retained. Non-parametric data was analysed using a Mann-Whitney U test. A p value of less than 0.05 was considered statistically significant.

Individual data are presented in Appendix 7 and referred to in the discussion chapter of the thesis.

3.5 Data Storage and Confidentiality

All study data collected was kept confidential. Data were anonymised with only the researcher being able to identify the data, using a unique code for each participant. Data from assessments were stored as paper records and transferred to electronic files. All departmental computers and any storage of electronic data were password protected and paper files were stored in a locked cabinet in the department. Data containing participants contact details were not stored on portable media devices.

Chapter 4 Qualitative Method

4.1 Introduction

This chapter begins with the justification for the qualitative research approach taken. The study follows a phenomenological approach, which has its origins in qualitative psychology (J. A. Smith, 2008). The chapter provides the rationale for the choice of a semi-structured interview approach. The processes of recruitment, consent and operational aspects of the study are then described. Following on from details of the data collection, the chapter concludes with a rationale and description of the data analysis process.

4.2 Justification for the Research Approach

4.2.1 Theoretical underpinning of the methodology

On examining the different approaches in qualitative research, phenomenology developed as the right fit for the approach of this study (J. A. Smith, 2008). Alternative approaches to data collection were considered, but rejected, as not being suitable to address the qualitative research aim and objectives. A case study approach was not feasible, as this would involve collecting a variety of sources of information over a sustained period of time, which was not possible within the constraints of the study. Grounded theory was investigated, but rejected as a method as the researcher was not looking to abstract a theory from the process (Cresswell, 2009), rather was aiming to understand the patients' experience. Ethnography, the study of a cultural group in a natural setting over a prolonged period of time (Cresswell, 1998), was also not the focus of this research and so also was discounted.

A phenomenological approach investigates the lived experience of a concept or phenomenon as described by the individuals themselves (Silverman, 2005). The researcher reduces the experiences to a central meaning or the 'essence' of the experience (Moustakas, 1994). The goal is not to describe a grand theory or develop a model, but to accurately describe a person's lived experience in relation to what is

being studied (Balls, 2009). Phenomenology is not only a qualitative strategy but a philosophical approach as well and has its origins in the German mathematician Edmund Husserl (1859-1938). The core philosophical basis of Husserl's approach was;

“ a rejection of the presupposition that there is something *behind* or *underlying* or *more fundamental than* experience, which should be immediately sought” (J. A. Smith, 2008)

Central to Husserl's ideas was 'bracketing' in which the researcher should set aside all prejudgments and his or her own experiences and rely on intuition, imagination to obtain a picture of the experience (Cresswell, 1998). Husserl's ideals are termed 'descriptive phenomenology'. Heidegger modified and developed Husserl's ideas in a different direction. He proposed it is impossible to rid the mind of preconceptions and approach the research in a neutral way, but by using an interpretive approach we can use our experiences to interpret those of others (Heidegger, 1962). Therefore, this study uses an interpretive phenomenological approach, which seeks to explore the individuals' experience, without 'bracketing' the researchers' prior experiences. Bracketing is highly difficult to achieve, and for this study was not desirable as it was appropriate for the authors' knowledge and experience in the field of neurological Physiotherapy, as well as feelings and emotions, to be a part of the process. This approach helps to both bring to light and reflect upon the lived experiences of the participants.

Interpretive phenomenology can also be described as a hermeneutic approach - the theory of interpretation (J. A. Smith, 2008), where the reading of a text/transcription is such that the intention and meaning behind appearances are fully understood from all perspectives (Moustakas, 1994). An interpretive phenomenological approach involves a 'fusion of horizons' (Koch, 1999), including that of the clinical and academic experience of the researcher and the participant's perspective. This enables an exploration of the participants' experiences, which in this mixed methods study could then be compared and contrasted with the quantitative data.

4.3 Data Collection Tool

4.3.1 Rationale for choice of data collection tool

Recognised qualitative tools were considered for this study. Observations were discounted, as the researcher was not exploring behaviour (Cresswell, 2009) and pragmatically the researcher was only going to be able to see the participants on one occasion. Despite xxx a focus group being a good forum for opening up discussion amongst the PwS and their lived experience, it could restrict the participants being able to convey the details of their personal story. Documents such as personal accounts and diaries can enable the researcher to obtain the language and words of participants (Cresswell, 2009; J. A. Smith, 2008), however there are no opportunities to explore comments further with this tool. Also diaries were not available from during the REAcH trial for analysis and comparison. A structured interview design was rejected as it confines the interviewer to the questions set, and so would not allow the interviewer the scope to explore the topic (J. A. Smith, 2008).

Smith (2008) reports the most common and exemplary method to collect data for an IPA study is semi-structured interviews.

“This form of interviewing allows the researcher and participant to engage in a dialogue whereby initial questions are modified in light of the participant’s responses and the investigator is able to probe interesting and important areas which arise”. (Smith 2009 p57)

Semi-structured interviewing also allows the ordering of the questions to be adjusted, as needed, so that the respondent path may be followed in the interview, (Cresswell, 2009; J. A. Smith, 2008). Interviews also allow the capture of historical information, addressing the qualitative objectives. The disadvantages of this method can be that not all people are articulate and perceptive, and the interviewer may bias the responses (see section 4.7.3.1).

The researcher chose face-to-face interviews, rather than telephone or internet interviews, as by using this approach emotions may be captured first hand, noting non-verbal information such as body language. Also being face to face may help to maintain focus in the interview. This method would also allow the researcher to build on the rapport the researcher had established with the participant in the REAcH study

(the researcher had previously met all but one of the participants in the Salford arm of the REAcH study).

Semi-structured interviewing was chosen as the qualitative data collection method as it has the benefits of the researcher being able to probe further on interesting areas and the ordering of the questions are less important, as the researcher can follow the respondent path in the interview, (Cresswell, 2009; J. A. Smith, 2008). A structured interview design was rejected as it confines the interviewer to the questions set, and so would not allow the interviewer the scope to explore the topic (J. A. Smith, 2008).

4.3.2 Development of the data collection tool

Development of an interview topic guide forces the researcher to think explicitly with regard to what the interview might cover (J. A. Smith, 2008). By planning ahead, the researcher can give thought to any difficulties that might be encountered during the interviews, such as question wording or sensitive areas for discussion, and how these might be handled. With preparation and a good knowledge of the topic guide the interviewer can be confident in the questions and concentrate on the responses. There are different types of questions that can be asked, some general, some more specific. Questions that might be more sensitive are left till further on in the interview, as the participant is likely to be more relaxed and comfortable than at the start of the interview.

The researcher can use a variety of questions such as questions to elicit experiences, behaviour, action and activity. Background questions can also be used to understand the participants' previous experiences, addressing one of the objectives of the study. Main questions can be used to begin topics and guide the interview. Probes can then be used to clarify and request further information on a topic. Probes need to be well timed, neutral and encouraging, not too inquisitive or demanding. Follow up questions can also be used to add depth by going back in time or going over points again (Bowling, 2009).

The content and questions of the semi-structured interview topic guide (see appendix 6) developed iteratively from the research aims (see section 2.11) and the literature review, along with the researcher's academic and clinical knowledge and experience, (Bowling, 2009). The REAcH research team also contributed to the process, with their combined expertise in the field to assist to help revise and test the questions and ensure relevance to the study aims. The questions and prompts were also checked with academic supervisors and the interview guide was part of the documentation submitted for ethical approval.

The literature review helped shape the questions. Questions were devised to explore the experience of having an intervention (the REAcH study) in the chronic phase post stroke. As upper limb FES is still an emerging technology, investigation of the participants' perceptions and experiences of the FES device were sought to assist in further usability, design and development of the technology (Hughes et al., 2011). The interviews also sought to capture any real or perceived changes in impairment, function or quality of life. The importance of the PwS's personal view on recovery was discussed by Jones et al (Jones et al., 2008).

“The domination of physical measures of recovery, used in stroke research, their value to the individual, may also be misleading in terms of what constitutes a successful recovery.” (Jones et al 2008 p507).

PwS may also value recovery in terms of social, emotional and psychological changes, as well as in terms of participation and valued activities (Jones et al., 2008; J.H. Morris & Williams, 2009). This led to exploring the participants' views of the facilitators and barriers to upper limb stroke recovery, which can be influenced by a range of individual internal and external factors (Jones et al., 2008). Barker et al (2007) noted that PwS tend to take a long term view of recovery and self-management is a factor in their recovery (Barker et al., 2007). The researcher wished to explore this area further in relation to participants' own strategies, beliefs, attitudes and approaches. The researcher agreed with Barker et al (2007) that it was important to explore factors other than medical diagnosis and comorbidities, as the stroke recovery constitutes a complex phenomenon.

A pragmatic decision was made not to pilot the questions with actual participants as the potential participant numbers were limited by those who had taken part in the REAcH study, which had already suffered some drop outs. Therefore, the decision was taken not to recruit any of the potential participants as a pilot, so the richness of the data from any one of the participants of the REAcH study would not be lost. This decision was checked with the researcher's academic supervisors and was clear as part of the application for ethical approval. The researcher did however reflect on each interview and used this process to refine subsequent interviews.

4.4 Recruitment and Consent

The interviews formed part of the study already described in Chapter 3. Details of inclusion and exclusion criteria, recruitment, and consent are in sections 3.2.3- 3.2.5.

4.5 Ethical Considerations

Ethical approval is described in section 3.2.4. However, special consideration was given to the interview process, during which, when discussing the stroke event and subsequent life changes that occur, it could be possible for the participant to become upset or emotional. The researcher would take appropriate action if this situation were to arise in line with professional behaviour. The researcher would reiterate to the participant in such a situation that they are free to pause or halt the interview, or indeed withdraw from the study should they wish.

4.6 Procedure of the Interview

The interviews were carried at the same appointment as the quantitative outcome measures for all participants. Participants were offered breaks whenever they wished and refreshments were also offered. The interviews took place in the same place as all their visits for the REAcH RCT, so the environment was a familiar one to all participants. This provided a neutral location, which was quiet, where the interviews could proceed without disturbance (Balls, 2009). The interviewees were given the

choice as to whether they wished to have anyone present during the interview, such as a partner. All interviews were audiotaped to enable the researcher to be able to transcribe the dialogue word for word (Cresswell, 2009; Sanders, 2014). The researcher also made brief field notes to assist with capturing the key points. The researcher used the interview guide, to ensure the interview covered all the questions the researcher wished to ask, and was useful to act as a reminder when the interview went in a different direction to return to the focus of the interview. The researcher made sure the participants were thanked for their time and effort at the end of the interview (Balls, 2009; Cresswell, 2009).

4.7 Data Analysis

4.7.1 Rationale for method of analysis

Analysis in phenomenological research follows a course of data reduction to determine the essence of the data. Thematic analysis, which is related to both phenomenology and grounded theory, was chosen as the approach to be taken with the interview data. Thematic analysis is an inductive approach, with the themes identified strongly linked to the data as they emerge. Any assumptions in the analysis are data driven and the data is not fitted into a pre-conceived model or framework (framework analysis). Thematic networks provide a simple analytical tool to organize the data, by unearthing the themes salient in a text at different levels and facilitating the structuring and depiction of these themes in a web like structure (Attride-Stirling, 2001). Thematic analysis shares the key features of any hermeneutic analysis (Attride-Stirling, 2001).

4.7.2 Process of analysis

Thematic networks provide a system of reducing the data and extracting 3 levels of themes (Attride-Stirling, 2001):

- Basic themes – the most basic / lower order themes in the text. On their own they say very little about the data and must be combined with other basic themes to represent an organizing theme.
- Organising themes – these are middle order themes, that clusters the basic themes into similar groups, so are more abstract and revealing of what is in the text than basic themes.
- Global themes – are super-ordinate themes that tell us what the texts as a whole are about within the context of the analysis. They are a summary and interpretation of the texts. There can be more than one global theme.

A thematic network is developed from the basic themes through to the global theme(s), depicted as a web like structure, illustrating how the themes are interconnected.

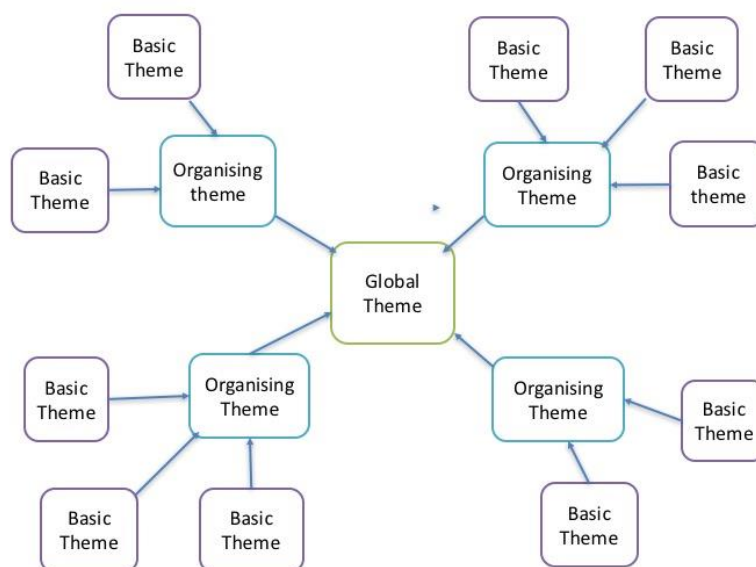


Figure 4.1 Structure of a thematic network

The network is a tool to aid analysis, not the analysis itself. The analysis can be divided into three parts: a) the reduction or breakdown of the text; b) the exploration of the text; and c) the integration of the exploration (Attride-Stirling, 2001). Figure 4.1 sets out the structure of a thematic network analysis (taken from Attride-Stirling, 2001) and the analysis process is described below:

Analysis Stage A: Reduction or Breakdown of Text

Step 1. Code Material

- a. Devise a coding framework
- b. Dissect text into text segments using coding framework

Step 2. Identify Themes

- a. Abstract themes from coded text segments
- b. Refine themes

Step 3. Construct Thematic Networks

- a. Arrange themes
- b. Select basic themes
- c. Rearrange into organising themes
- d. Deduce global theme
- e. Illustrate as thematic network(s)
- f. Verify and refine network(s)

Analysis Stage B: Exploration of Text

Step 4. Describe and Explore Thematic Networks

- a. Describe the network
- b. Explore the network

Step 5. Summarize Thematic Networks

Analysis Stage C: Integration of Exploration

Step 6. Interpret Patterns

Transcribing the data was out-sourced to a competent person with training in the transcription of audio recordings. However from the start of the process of both data collection and analysis the researcher kept notes of her reflections and thoughts (Richards, 2005). This enabled the researcher to make notes on emerging themes and relate to other parts of the thesis and reflect on the process. Each stage of the process was documented to provide an audit trail throughout the analysis as suggested by Sanders (Sanders, 2014).

The audio-recordings were all listened to at least once and the transcripts read at least 3 times each before the researcher commenced coding to enable the researcher to immerse herself in the data. No computer software was used for the coding, as Richards (2005) argues that this approach is “...not a substitute for reading and thinking about your data” (Richards, 2005).

As there were no theoretical interests guiding the analysis, the coding method chosen was to allow the text to generate the salient issues as they arose (Attride-Stirling, 2001). The codes generated were discrete enough to avoid redundancy but global enough to be meaningful (Attride-Stirling, 2001). The text was then dissected, using the codes, with the text segments ranging from a few words to a whole passage. Themes were then extracted from the code segments and related codes were grouped together to further reduce the text. The process then moved towards construction of the network, describing and exploring it, leading to the final phases of summarizing the network and interpreting patterns as set out above. The findings of the analysis and the thematic network are described in Chapter 6.

As this study was a mixed methods study, the researcher then considered the thematic network in relation to the quantitative results, which will be discussed in Chapter 7.

4.7.3 Verification

The process of verification for the qualitative part of study was ongoing throughout the data collection, analysis and report writing. Verification related to a phenomenological approach involves the lens of both the researcher and outsider reviewers (Cresswell, 1998).

4.7.3.1 Researcher perspective

Clarification of researcher bias – As the researcher used an interpretive phenomenological approach, the experience of the researcher was relevant. The researcher has worked in neurological Physiotherapy within the NHS for 11 years, treating stroke patients on acute stroke units through to the community setting, and is aware of issues associated with upper limb stroke recovery. The researcher’s

knowledge and experience as a Physiotherapist has shaped her views, alongside her more recent role as a researcher in upper limb rehabilitation technology. The researcher was able to bring this knowledge from theory and practice of the subject area, along with a knowledge of the participants from being a researcher in the REAcH study, to illuminate the voices of the participants.

The researcher aimed to reduce social desirability bias by carefully wording the questions and by direct reassurance to the participants that there were no right and wrong answers and that the researcher was interested in their thoughts and perspective, whatever they were. The researcher used these strategies to seek the voice and perspectives of the participants throughout the interviews. The interview guide acted as a guide only, providing prompts, and by adopting a conversational style to the interviews the aim was to allow the participants to speak freely about the subject. By using a phenomenological approach, the researcher sought to gain a better understanding of the patient's experiences and perspectives.

As part of the verification process, following analysis, the researcher sought to ask the following questions of herself, as the qualitative researcher.

1. Did the interviewer influence the content of the subjects' descriptions in such a way that they do not truly reflect the subjects' actual experience?

Member checking - The researcher was careful to summarise participant responses where possible, and to question further within the interview where required, in order to ensure the participants actual experience was reflected and recorded accurately. This was done within the interview to increase truthfulness. The researcher also sought to build on the rapport established with the participants during the REAcH study, in order to obtain honest and open responses. Further member checking was not carried out outside of the interviews, due mainly to a significant time lapse between the interviews and the analysis.

2. Are the transcriptions accurate and do they convey the meaning of the oral presentation in the interview?

The researcher checked all transcriptions against the original audio recording to confirm accuracy and that the meaning was conveyed. The researcher was also carried out all interviews, so was able to use her memory of the interviews, and knowledge of the context of the data (including field notes) to add rigor to this process.

3. In the analysis of the transcriptions, were there conclusions other than those offered by the researcher that could have been derived.

As part of a phenomenological approach, the interviewer brings their own experience and knowledge of the subject area to the interview in a merge of 'horizons'. It is therefore pertinent that the interviewer carries out the analysis. The researcher referred back to the actual transcripts repeatedly to ensure quotes were not taken out of context. The researcher also sought to provide rich interpretations of the data to allow the reader to make decisions regarding transferability. The data analysis process was monitored by the researcher's academic supervisor and an audit trail was provided by the researcher (see section 4.7.3.2).

4.7.3.2 *Outside reviewer perspective*

As a novice researcher, and in line with good practice, a process of peer review and debriefing was used as an external check of the research process. This was done by the researcher's academic supervisor, an experienced qualitative researcher, where the aim was to keep the researcher honest and ask questions regarding methods, meanings and interpretation. The researcher's supervisor checked the analysis at all stages of the process, to check the coding, emerging themes and meanings, and an audit trail was available to the supervisor to enable this. Themes were confirmed as being a reasonable interpretation by the supervisor.

4.8 Summary

This chapter draws together the philosophical approach taken, with the rationale and development of the data collection tool used. Finally, the analysis procedure was summarised and details of verification given.

Chapter 5 Quantitative Results

5.1 Recruitment

The Salford arm of the REAcH recruited 28 participants and there were 7 drop outs and 1 incomplete data set, leaving 20 potential participants to be recruited for this study. Four of the first potential participants came to the 12 month follow up point, when the researcher was on maternity leave and hence these were not contacted about the study.

Information was sent out to the 16 remaining potential participants. Nine participants were recruited, 1 made contact and was unable to participate as she had moved away from the area. There was no reply from 4, 1 was contacted via the phone after the 2-week period and declined to be involved and another agreed to attend for the appointment but did not attend the appointment and did not want to reschedule it. The figure below shows the recruitment of participants for this study from the available participants from the Salford arm of the REAcH study.

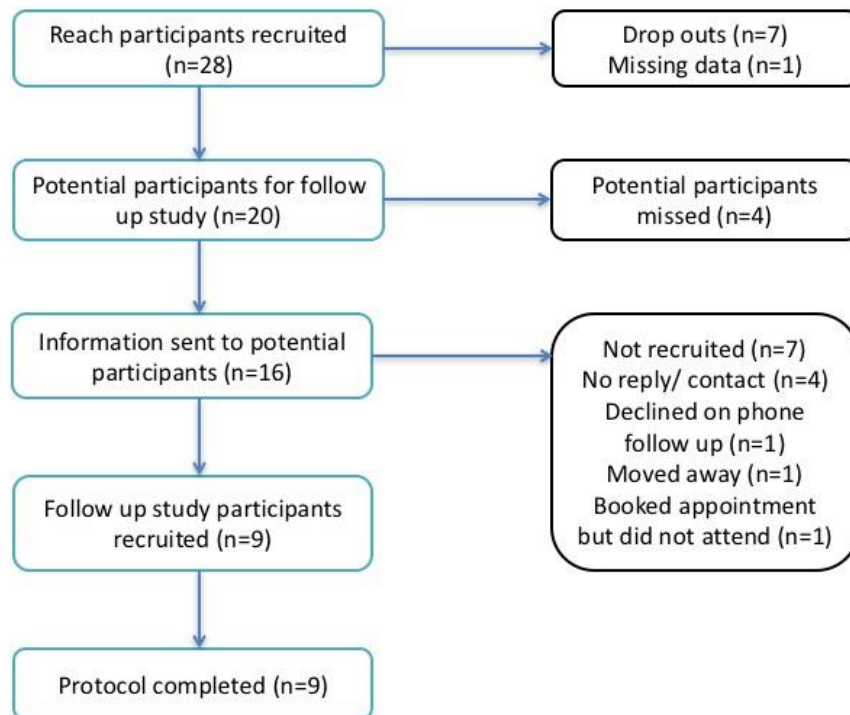


Figure 5.1 Recruitment for the follow-up study

5.2 Demographics

5.2.1 Baseline demographics

The table below shows the demographic information for all the nine participants of the 12-month follow up study by group, at the time point of entering the REAcH study.

Participants	Age	Time Since Stroke (months)	Dominant Hand	Affected Side	Male/ Female	Lives With
Exercise						
38	62	31	L	R	F	Husband
41	47	24	R	R	F	Partner
43	59	120	R	L	M	Family
51	64	6	R	R	M	Family
58	70	46	R	R	M	Wife
FES						
42	59	51	R	L	M	Partner
44	61	164	R	R	M	Family
54	39	49	R	R	M	Friend
55	78	72	L	R	F	Alone
Mean	59.9	62.5				
Range	39-78	6-164				

Table 5.1 Demographics of all participants on entering the REAcH study

5.2.2 Demographics baseline comparison

	Reach Study (n=44)	Follow-Up Study (n=9)
Age (years)	60.1 (14.3)	59.9 (11.5)
Time since stroke (months)	47.5 (48.7)	62.6 (49.9)
Dominant hand (%right)	93.2	77.8
Stroke side (%right)	34.1	77.8
Male / Female (%male)	59.1	66.7

Table 5.2 Baseline demographics of full REAcH cohort and follow up cohort

The 12-month follow up group is similar in age and representative of the full REAcH cohort (all measures taken at week -6). The follow up group had a greater average time since stroke when compared to the whole cohort, with a difference in the means of 15.1 months. There was a substantial difference between the groups in terms of the

numbers of right-sided strokes, with more in the follow-up group, and more participants in the follow up group were dominant side affected.

5.3 Baseline Measures

5.3.1 Baseline measures - REAcH and 12-month follow up study cohorts

	REAcH		12 month study	
	Mean	Range	Mean	Range
ARAT	21.1 (8.6)	0-38	25.6 (9.9)	7-37
Box & Block	12.6 (10.5)	0-40	14.1 (13.0)	0-36
MAS Elbow	1.5 (1.1)	0-4	1.7 (1.2)	0-3
MAS Wrist	1.2 (1.2)	0-4	1.3 (1.5)	0-4
MAS Fingers	0.9 (1.3)	0-4	0.9 (1.4)	0-4
Fugl-Meyer	32.9 (9.1)	17-58	36.1 (11.8)	20-58
SIS 7	22.4 (15.1)	0-70	18.9 (22.7)	0-70
SIS 9	54.4 (17.6)	20-85	56.9 (16.8)	32-80

Table 5.3 Baseline measures of REAcH and follow-up studies

Table 5.3 shows the baselines measures for the full REAcH cohort and the 12 month follow up (measures taken at week -6). There is no overall trend in the difference between the groups, suggesting the 12-month follow up group is representative of the full REAcH cohort at baseline.

5.3.2 Comparison in week 0 – 12 outcome measures between REAcH and 12 month follow up cohorts

	Reach Study		12 follow up	
	Mean change	Min, max	Mean change	Min, max
ARAT	1.9 (4.2)	-6, 14	0.6 (1.9)	-3, 3
Box & Block	0.7 (3.9)	-8, 9	0.0 (5)	-8, 7
MAS – Elbow	-0.2 (0.75)	-2, 1	-0.1 (0.8)	-1, 1
MAS – Wrist	-0.2 (0.7)	-2, 1	-0.3 (0.9)	-2, 1
MAS – Fingers	-0.3 (0.7)	-2, 1	-0.1 (0.6)	-1, 1
Fugl – Meyer	4.2 (5.9)	-7, 19	2.1 (4.0)	-3, 9
SIS 7	9.6 (16.4)	-30, 50	5.9 (16.9)	-30, 20
SIS 9	6.2 (10.6)	-20, 32.5	12.5 (10.3)	0, 32.5

Table 5.4 REAcH and 12 months follow-up cohorts - week 0-12 change

Comparison of changes in outcome measures from week 0 to week 12 between the Reach study group and the current study group. The follow up study tended towards

smaller improvements in ARAT, Box & Block and SIS 7 scores over the initial 12-week study period and a greater increase in SIS 9, the differences in both groups are small and overall there are no striking differences, suggesting the study groups response to intervention was similar to the REAcH group overall.

5.4 Statistical Analysis of Follow Up Cohort (n=9)

	Week 0 Mean (SD)	Week 12 mean (SD)	Mean Diff 0 to 12	P value	95% confidence interval	Week 64 Mean	Mean diff 12 to 64	P value	95% confidence interval
ARAT	24.89 (9.43)	25.44 (10.26)	0.56	0.40	-0.89 to 2.00	25.89 (10.90)	0.45	N/A	N/A
Fugl-Meyer	36.67 (12.30)	38.78 (11.2)	2.11	0.15	-1.00 to 5.22	39.44 (12.85)	0.66	N/A	N/A
Box & Block	13.78 (12.65)	14.11 (14.63)	0.33	0.85	-3.70 to 4.36	14.56 (13.88)	0.45	N/A	N/A
MAS Elbow	1.22 (1.09)	1.11 (0.78)	-0.11	0.68	-0.71 to 0.49	1.44 (1.23)	0.33 (0.87)	N/A	N/A
MAS Wrist	1.11 (1.17)	0.78 (0.67)	-0.33	0.66	N/A	1.22 (1.39)	0.44 (0.88)	N/A	N/A
MAS Fingers	0.78 (0.97)	0.67 (0.70)	-0.11	0.97	N/A	0.66 (0.78)	-0.11 (0.60)	N/A	N/A
SIS 1	59.0 (17.4)	56.3 (15.9)	-2.70	0.51	-12.1 to 6.6	50.00 (14.66)	-6.25 (15.93)	N/A	N/A
SIS 2	80.2 (11.9)	75.8 (15.5)	-4.40	0.17	-11.1 to 2.3	73.02 (15.58)	-2.77 (12.34)	N/A	N/A
SIS 3	79.6 (19.0)	78.1 (18.8)	-1.50	0.78	-13.7 to 10.6	83.33 (16.19)	5.24 (19.60)	N/A	N/A
SIS 4	72.6 (27.1)	75.8 (22.7)	3.20	0.26	-2.9 to 9.2	77.78 (18.36)	1.99 (11.59)	N/A	N/A
SIS 5	65.3 (13.8)	66.1 (12.8)	0.80	0.84	-8.1 to 9.8	69.72 (9.22)	3.61 (12.93)	N/A	N/A
SIS 6	77.8 (16.8)	78.4 (14.7)	0.60	0.93	-14.6 to 15.8	77.46 (17.47)	-0.93 (14.42)	N/A	N/A
SIS 7	26.11 (26.43)	31.11 (19.97)	5.00	0.40	-8.03 to 18.03	25.56 (23.11)	-5.55	N/A	N/A
SIS 8	52.4 (17.7)	66.7 (18.5)	14.30	0.03	1.7 to 26.8	75.0 (13.6)	8.30	0.22	-6.1 to 22.8
SIS Recovery	51.67 (16.39)	64.17 (14.03)	12.50	0.0066	4.57 to 20.43	64.70 (18.33)	0.50	0.89	-7.9 to 8.9

Table 5.5 Statistical analysis follow-up group

In terms of the ARAT, Fugl-Meyer, Box and Block and Modified Ashworth Scale outcome measures, there were no statistically significant differences ($p > 0.05$) in the group over the intervention period (weeks 0 to 12) during the REAcH study. Any further statistical analysis of these measures was then not appropriate. In terms of the

self-report measures, the seventh domain of the Stroke Impact Scale (SIS) which concerns hand function also did not find a statistical significant change from weeks 0 to 12 in the REAcH study ($p = 0.40$). However, the participation domain (8) and the domain looking at self-reporting of overall recovery, saw statistically significant improvements by the end of the intervention period in REAcH ($p = 0.03$ and ($p = 0.0066$) respectively. This enabled further analysis to ascertain if this improvement was maintained at the follow up (week 64). The results showed no statistically significant change from week 12 to 64 and suggesting the gains made in the REAcH study were retained by the follow up study cohort.

5.5 Summary

Nine participants were recruited for this study. The follow up group was representative of the full REAcH cohort in age, but the follow up group had a longer mean time since stroke.

As there were no between group differences found in the REAcH study, statistical comparisons of data between two smaller groups in the follow up study were not explored and the nine participants were analysed as a single group. The follow up cohort ($n=9$) showed no statistically significance differences between weeks 0 and 12 (end of the intervention) in the ARAT, FM, Box and Block or MAS. Statistical analysis was not therefore carried out on the scores from week 12 to week 64. The first seven domains of the SIS including the seventh – hand function, showed a similar result with no statistical significance differences seen. However, the mean of the self-reported recovery domain score of the SIS improved from 51.7 to 64.2 ($p = 0.006$) and the SIS participation domain from 52.4 to 66.7 ($p= 0.03$), both were maintained at follow up. Some changes in study measures were seen at an individual level (see Appendix 7) which in cases exceeded the MICD for that measure, some maintained these changes, or showed continued improvement over the 12 month follow up.

Chapter 6 Findings from the Thematic Analysis of the interviews

6.1 Introduction

This Chapter presents the findings from the interviews with participants, following analysis of the interview transcripts using a thematic approach and thematic networks were developed. The analysis of the data revealed codes, which were organised into basic themes within overarching ‘organising’ themes (Attride-Stirling, 2001). Within each organising theme (n= 7) there were up to 7 basic themes (Tables 6.2, 6.3, 6.5-6.9). These tables also detail the codes that emerged from the process of data reduction, the issues discussed and the creation of the basic themes. The organizing themes were then grouped under two global themes (Tables 6.1 and 6.4). Where quotes are used as exemplars from the interview transcripts, they are referred to with the participant number appearing in bold, followed by the line number(s) in the transcript, so all references and quotes can be traced directly back to the original transcript. The interviews ranged in length from 6 minutes 20 seconds to 32 minutes and 45 seconds, with an average of 16 minutes and 26 seconds. Some of the participants had speech difficulties and consequently some of the quotes are short.

Organising Themes	Global Theme 1
<div>1. Perceptions and experiences of voluntary triggered FES in the REAcH study</div> <div>2. The interventions in the REAcH study had a positive effect on most of the participants</div>	The experience of participating in the REAcH chronic stroke study was mostly a positive one

Table 6.1 Global theme 1

6.2 Global Theme 1: The Experience of Participating in REAcH, a Chronic Stroke Research Study, can be a Positive One

6.2.1 Organising Theme - Perceptions and experiences of voluntary triggered FES in the REAcH study

The process of organizing the codes, issues discussed and basic themes that emerged in this organising theme is detailed in Table 6.2

Codes	Issues Discussed	Basic Themes
Investigated FES	Seven out of nine did not investigate FES after the study 1 participant was assessed for lower limb FES, but was not appropriate 1 participant was involved in another upper limb FES study	Low level of awareness/ knowledge of FES
Awareness/ knowledge of FES	References made to FES 'What's FES?' and 'The electrical stuff' Has lower limb FES already, study did not prompt them to further investigate upper limb FES	
Usability and reliability issues	Device was quite useful Usability issues – caused stress Device did not work properly Donning and doffing was frustrating Difficulty with putting electrodes on Did not like the thought of the electric impulses Did not feel they benefitted from the device Difficulty triggering with a severe paresis	Negative experiences, usability and reliability issues with the FES device
Positive experiences with the device	Overall concept of FES is interesting and a good one Triggering was OK Nice to see fingers can move Wireless would be a good feature Using the device seemed to trigger some positive changes in the upper limb	The overall concept of FES and the device was good, with positive effects from using the device
Specific positive effects reported	Nice to see the fingers can move Reports 25% improvement in wrist and elbow Increased sensation Increased proprioception Decreased swelling Improved appearance of the upper limb	

Table 6.2 Organising theme - perceptions and experiences of voluntary triggered FES in the REAcH study

6.2.1.1 Basic Theme - Participants generally showed a low awareness / understanding of FES

As part of the semi-structured interview questions (Appendix 6) all participants were asked if they had gone on to further investigate FES for their upper limb in the last year since their involvement in the REAcH study. Seven out of the nine had not done this. One participant (in the exercise group) had investigated FES for his lower limb with a National Health Service (NHS) FES service, but had been assessed a FES trained Physiotherapist as not appropriate for it. Another participant (who was in the FES group) had been involved in another upper limb FES research study with the same research team. Participant 55 had lower limb FES already but had not pursued upper limb FES. It is also worth noting that participant 55 was in the FES group, but in the interview when asked which group she was in, she stated she was in the exercise group, and made no comment on FES. It is unknown why this was reported incorrectly and as the researcher did not know which group the participants were in, there was no reason to question or clarify this. It is interesting that she made no reference to the FES. Further to this, seven out of nine had not investigated FES, indeed two participants said;

“What’s FES?” (38; lines 5-6)

“FES?” (51; line 18)

This seems to imply a low awareness or knowledge of FES. Four out of the nine participants used the device and so the other five in the exercise group would only have seen that device at the assessment appointment and would not have ever used it (although they would have experienced stimulation, using a more basic stimulator, the Odstock a Micro Stim at assessment). Hence, the participants from the exercise groups’ exposure to the FES device or any other FES was minimal and therefore could account for the low level of interest or awareness in the technology. It also highlights that upper limb FES is not commonplace in rehabilitation in the UK, as FES only tends to be used in specialist FES services or in the context of research.

6.2.1.2 Basic Theme – There were some negative experiences, usability and reliability issues experienced with the FES device.

There were some negative experiences/aspects of the device noted by three participants. This is reflected in the comments made as one participant who describes the FES as ‘electrical stuff’ (42; line 14). Further, he went on to say;

“Well I thought it was quite useful to have but I opted out because I just couldn’t cope with the stress of putting that thing on in the end...”. (42; lines 24-8)

Participant 54 also experienced some issues with donning the electrodes. Participant 42 went on to suggest improvements to the design;

“I said at the time that if they possibly had a clamp to put it in rather than going that way, you know something like that, it just shouldn’t be too difficult, to have one snap thing.” (42; lines 36-39)

Participant 54 thought the device would be better if it was wireless. User involvement in design of technologies is an important area (Williamson et al., 2015). The findings illuminate the importance of design, reliability and usability in rehabilitation technologies. This subjective information from the interviews corresponds with the results from the Use of Devices Questionnaire (UDQ) in the REAcH project (appendix 2). Participant 42 reported he did not like the sensation, which although less common can be a drawback to using FES, and so influenced this participants’ ability to experience the technology;

“I was beginning to feel aversion you know, against the electricity you know, I don’t know it’s probably my over reaction to it”. (42; line 46)

Participant 44 also reported issues with the device, stating that;

“...it didn’t go marvellous”. (44; line 9)

Unfortunately, there was a malfunction with this device, which contributed to his negative experience. Participant 54 found that when the device was in exercise mode it worked well for him, but when it was programmed in trigger mode he had

difficulties, which he put down to insufficient movement in his hemiplegic arm to trigger the device. His mother postulated it would have worked better if the sensors had been more sensitive, or set up differently;

“It seemed to come in further down the route than he could do his arm, say it came in there and triggered, but he could only move his arm to here”. (Participant 54’s mother; lines 59-60)

This participant met the criteria for study entry, but had the most severe paresis of all the participants at the Salford site, so it appeared that he struggled with the voluntary triggering of the device, which was set at a requirement of approximately 45 degrees of shoulder flexion to trigger the device to deliver FES. Systems are currently in development that can use various different triggering methods and so give more options for PwS with severe upper limb paresis, whilst maintaining the option of using voluntary effort (C. Smith, 2015).

6.2.1.3 Basic Theme – The overall concept of the FES device was good, positive effects of using the device were reported.

Specific benefits were reported as being attributable to the device and some participants considered the concept of the device. Both Participant 42 and 54 reported that the concept was good;

“It was quite usefulit was interesting, yeah, I’m sure if the machine had worked properly it would be worthwhile pursuing”. (42; lines 24-8)

Participant 54 when asked about his thoughts on FES overall;

“...good ... yeah wow”. (54; line 54)

Participant 42 seemed to have no problems with the triggering;

“I think when I had it on, it seemed to trigger all right”. (42,34)

Despite the reported difficulties revealed by Participant 42 he reported a positive experience of being able to see movement in his paretic arm;

“Well I mean it’s nice to see that you suddenly your fingers can move”. (42; line 41)

Despite the issues with the triggering of the device both participant 54 and his mother commented on the positive impact the FES device had on him.

“I think he felt, we both did really, that he got quite a bit more feeling in it (his arm) from that, it seemed to trigger the feeling coming back, so that when you touched the arm, you know not necessarily but you know but he could feel the arm...it seemed to kick start the feeling in the arm” (Participant 54’s mother; lines 89-92,97).

In the year since he completed the REACH study participant 54 reported that he had been involved in another FES project. This involved four sessions using a multi-channel system for functional tasks. He reports a 25% improvement in his wrist and elbow in the last year, and reported a number of changes, namely: increased sensation, increased proprioception, and an improvement in the general feeling in his arm, an improved appearance;

“...less blue”. (54; lines 115-7)

“...less swollen”. (54; lines 118-9)

When asked what else he had done or what he felt was attributable for these changes, both the participant and his mother reported the main factor was use of the FES device;

“He has been going to BASIC for 3, 3 ½ years (a specialist gym for people with a brain injury) prior to going on this (the FES device) and it just seems to going on this, (referring to the FES device) it could be a coincidence” (54; lines 144-6).

6.2.2 Organising Theme – The interventions in the REACH study had a positive effect on most of the participants

In line with previous FES studies, as noted in the literature review, the authors study did not indicate a clear advantage of one type of intervention over another (see chapter 5 results). In the REACH study the non FES group was described as a control, when the participants in this groups were receiving an intervention of Physiotherapist led stretching, exercise and task specific practice. It is evident from the results (chapter 5) and the interview data that some participants responded to this input. This organising theme reveals the participants' perception of the benefits of an upper limb intervention in chronic stroke.

The process of organising the codes, issues discussed and basic themes that emerged in this organising theme is detailed in Table 6.3.

Codes	Issues Discussed	Basic Themes
Seeing a physiotherapist	Seeing the physiotherapist was useful Advise was good – told to 'use it' Advise had an impact Motivational Felt supported It was positive to have a commitment to doing the exercises, by returning to see the Physiotherapist	Seeing a Physiotherapist in the chronic phase of stroke had a positive impact on participants
Exercises given in the study	The exercises worked and were good Having the exercises written down was good	Benefits were reported from the interventions in the REACH study, which had a positive impact on participants
Functional changes	Still doing the exercises 1 year on	
Benefits to being in a study/ intervention in chronic stroke	Able to tie hair up now Turning lights on Enjoyable Decreased tone Using it more now than they were before Sense of achievement	Not all participants reported positive effects from the REACH study
Unsure of effect/ negative issues	Has gratitude for their own positive attitude Unsure if involvement had any benefit Husband of a participant reported disappointment of not being in the FES group	

Table 6.3 Organising theme - the interventions in the REACH study had a positive effect on most of the participants

6.2.2.1 Basic Theme – Seeing a Physiotherapist in the chronic phase of stroke had a positive effect on participants

Two participants reported that being supported by the Physiotherapist who delivered the interventions in the REAcH study as being very useful;

“Talking to (the physiotherapist) is very useful... (the physiotherapist) instilled in (participant 38) to use her hand all the time ...gave us a hand, it motivated her”. (Participant 38’s husband 38; lines 129-31).

“...quite enjoyable as well it makes you do the exercises for me it is quite beneficial because you are made to do it”. (41; lines 218-220)

She discussed seeing a therapist as motivational and finding it helpful to have someone checking on progress. This is in line with the findings of Jones et al (2008) who in a qualitative study of reasons for recovery after stroke found some participants described the motivation and encouragement provided by therapists, seeming to induce a feeling of hope and confidence (Jones et al., 2008). Anecdotally one of the participants was reported to have said outside of the interviews “All you need is one hour with the Physiotherapist”. This underlines the significant impact such an intervention can have in this population.

6.2.2.2 Basic Theme – Benefits were reported from the interventions in the REAcH study, which had a positive impact on participants

The participants generally found their involvement in the study to be a positive and beneficial experience (participants 38, 41, 42, 43, 53, 54, 58). The benefits reported from the participant’s involvement with the REAcH study ranged from physical to psychological, emotional and educational. There were comments made on the written exercises which were given out in the REAcH study;

“I thought the paper that I got from the study was quite useful”. (42; line 84)

“It (her arm) improved with the exercises and whilst I was doing it all the time on a regular basis but I would say that it (her arm) has

gone slightly backwards because I am not exercising it all the time, so it is my fault, if I carried on the exercises twice a day or whatever I was doing, two lots twice a day I reckon I would be, quite rightly I would be even better off because you do tend to get lazy because it does get tedious". (41; lines 15-20)

"yeah it was good, the exercise was actually quite good...but I didn't carry it on, you know, but you don't tend to think you know that you should do, you just kind of get on with your life basically and kind of enjoy yourself". (43; lines 16, 18-20)

The impact of the exercises was reported by participant 41 in achieving a specific functional task, and maintaining this ability at the follow up one year on;

"...It does show it did work, I could tie my hair up, I could never ever tie, I am not saying I can do it great but I could get a bobble in, which I could never do before I started the REAcH study". (41; lines 22-24)

The physiotherapist instilled in participant 38 to use her upper limb all the time (38; lines 129-31) and she reported using it more since her inclusion in the study and gave an example;

"I switch the lights on". (38; line 41)

The interviewer asked participant 38 if she was trying to do more things with it these days, to which she replied "yes". She also gave a positive answer when she was asked if she felt it helped by being in the study. When asked how she felt it helped she replied;

"They told me to use it". (38; line 49)

Whilst unsure of whether he benefitted from the study participant 51 reported he was still carrying out the study prescribed exercises a year later (51; line 30). Hence the exercises appeared to have had an impact. Participant 43 reported his involvement had impacted on the tone in his hand;

"My hand actually felt not as clamped up after listening to you saying about how you are supposed to stretch everything you know,

that's maybe why isn't it because I was moving this hand". (43; line 22-24)

Another participant (58), felt he was grateful for being part of the study as he realized he was fortunate to have his positive attitude and outlook towards dealing with his stroke.

"I'm very grateful to be able to be involved in something like this, because you realise that there is such a lot of people who have a different attitude to things and I think it's that, that has probably helped me to get as far as I have done" (58; lines 219-222).

He felt that his attitude and how he approached things was very much related to how his recovery had progressed (see section 6.3.2), which concurs with other studies such as Jones et al (2008). He has also noted that inclusion in the study had given him a sense of achievement (58; line 234).

6.2.2.3 Basic Theme – Not all participants reported positive effects from the REAcH study

Participant 51 was unsure of the positive effect of the study for him;

"I am not sure it had any effect on me whatsoever apart from the fact it forced me to do exercises as part of the study...which I probably still do some of them, not all of them. So I am not sure that it had any effect on me whatsoever". (51; line 30-34)

Participant 38's husband commented that he was disappointed that his wife was not in the intervention group, but this can be expected when there is an intervention group and a control group;

"It would have been nicer if she could have used that FES but I think she would have made more progress with that with what she actually did, I do honestly. It's a shame she couldn't use it". (Participant 38's husband; lines 118-121)

6.2.2.4 Summary

In summary, involvement in the REAcH research study was described as a positive experience by most of the participants, the majority describing specific individualised benefits. There were some reliability and usability issues with the device, but the overall concept was seen as a good one, and specific benefits could be attributable to the FES. Seeing a physiotherapist in the chronic stage of stroke was seen as highly beneficial and a significant number of PwS in the study were not receiving therapy (see section 6.5). The impact of being involved in the REAcH study on the participants was on a physical, educational, emotional and psychological level. Some of these themes will be explored in more depth in this chapter. The basic and organising themes that developed global theme 1 are illustrated in a thematic network (figure 6.1).

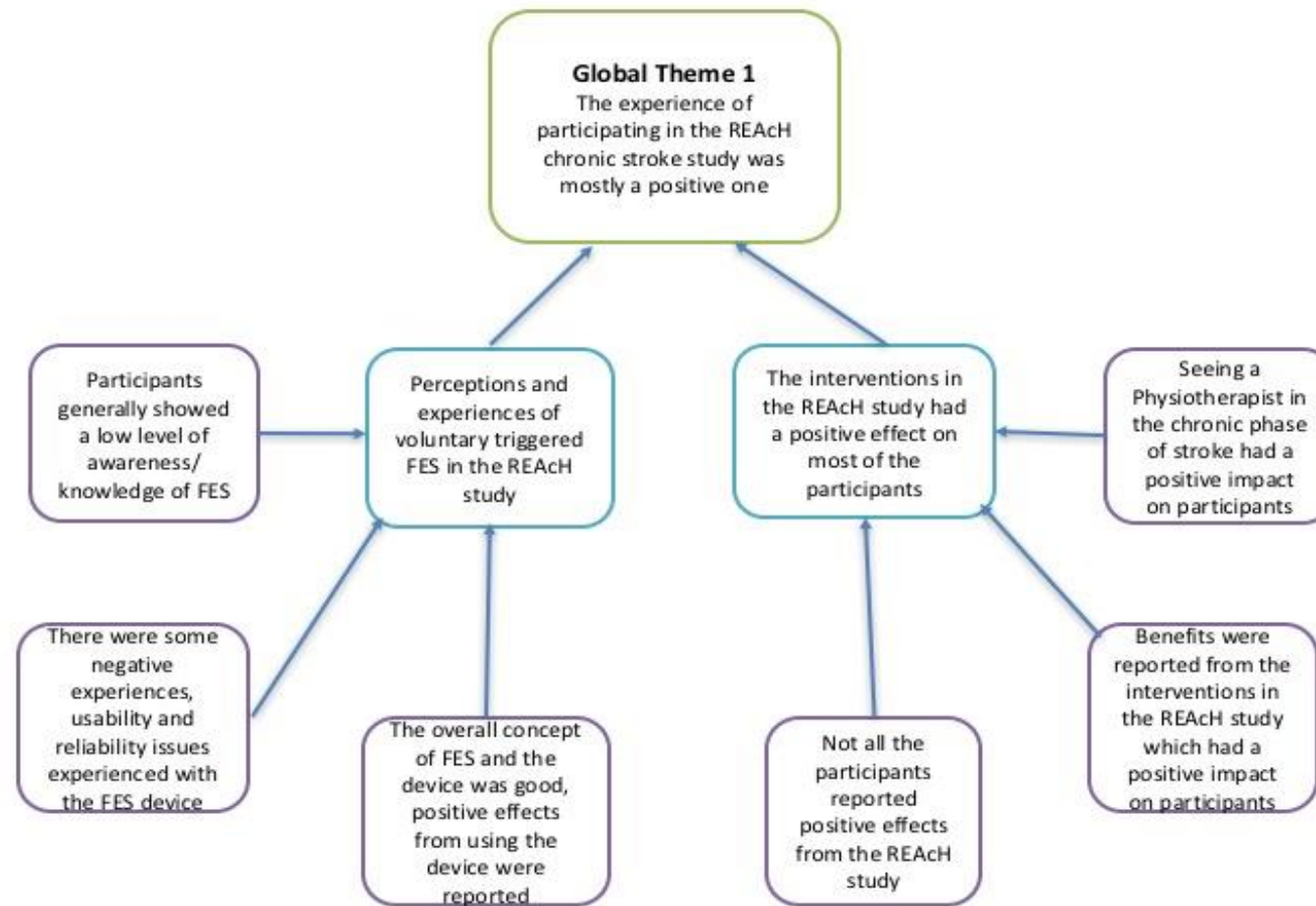


Figure 6.1 Thematic Network: Global theme 1

6.3 Global Theme – Upper Limb Recovery is Not Just a Physical Process

This global theme illuminates the factors, other than the interventions in REAcH, which were significant in the upper limb and general recovery that emerged for these participants. This theme relates directly to the third aim of the thesis, and contributes to the first aim also, as it provides the participants' perceptions of the factors involved in their upper limb recovery. Individual recovery status, education and a positive approach were found to be key factors for these participants. Psychological, educational, emotional and social factors were also found to contribute and provide challenges to an individual's recovery. Table 6.4 demonstrates how the organising themes for global theme two.

Organising Themes	Global Theme 2
<ul style="list-style-type: none">• Participant's perceptions of their upper limb recovery• Personal attitudes, approaches and beliefs are important aspects of recovery• Education is important• A variety of internal factors are perceived by the participants to contribute and provide challenges to their recovery• A variety external factors are perceived by the participants to contribute and provide challenges to their recovery	Upper limb recovery is not just a physical process.

Table 6.4 Global theme 2

6.3.1 Organising Theme – Participants' Perceptions of Their Upper Limb Recovery

This theme is clearly woven throughout the interviews. This is a reflection of the fact that one of the primary aims of the interviews was to determine what factors could have played a part in the recovery of the participant's upper limb, and their perceptions related to recovery as a whole.

The process of organizing the codes, issues discussed and basic themes that emerged in this organizing theme is detailed in Table 6.5 overleaf.

Code	Issues	Basic Themes
Status of upper limb recovery at interview, since last seen in the REAcH study	Worse Initially better, may have gone slightly backwards No change Has improved Nothing specific but has improved Definite improvement Specific improvement	In the follow up period, most participants had improved or stayed the same in their level of upper limb recovery
Still improving in chronic phase	Has improved from when had the stroke to now Continues to improve and is 5 years post stroke Unbelievable recovery so far Feels they are still improving	There is a mix of participants who are actively still trying, hope for further improvement and perceive they are improving. There are those who are not improving or trying and conflict exists for others
Thoughts on hope in relation to their recovery	Hopes they will still improve further Hopes for more improvement, but has been told might be as good as going to get Does not believe there is no recovery after 2 years Discarded hope/ still trying Discarded hope of the upper limb coming back Get used to it not working	
Not actively trying / come to terms with it	Not actively trying to improve upper limb Believes brain is dead so upper limb won't improve (related to information and knowledge) Did try a lot but it has been 15 years' now Has come to terms with it	
Still trying		
Conflict	Still actively trying to improve Same sentence discards hope, but also might still try	

Table 6.5 Organising theme - participants perceptions of their upper limb recovery

6.3.1.1 Basic Theme- In the follow up period, most participants have improved or stayed the same in their level of upper limb recovery

Four of the participants reported they felt their arm was no different to how it was one year ago, at the end of the intervention period in REAcH (participant's 42, 43, 44, 55). Participant 38 reports are mixed, as she felt her thumb was worse than it was one year

ago and she had some aching in her shoulder, but did report she was using it more than she was a year ago. The remaining four participants all felt they had improved in various ways (participants 41, 51, 54, 58). Participant 51 when asked if his arm had stayed the same, got better or got worse, he replied

“...it’s improved, definitely improved”. (51; line 37)

Participant 58 was talking about continuing to improve and when asked if he does, he replied

“Oh yes I do. I have a positive attitude (it sounds very good that!) to it. I can very easily see that with the negative attitude I wouldn’t have improved as much. I don’t think any advice would have been taken”. (58; line 50-52)

Participant 58 when asked to give examples of any change in the last year replied;

I think I’ve got a bit more flexible and adaptable”. (58; line 83)

Participant 54 reported a 25% improvement in his arm in the time period. However participant 41 felt;

“It improved with the exercises and whilst I was doing it all the time on a regular basis, but I would say that it has gone slightly backwards because I am not exercising all the time...”. (41; lines 15-17)

As a group, nearly half had reported some improvement in the last year since the intervention in the REAcH study. The majority of the rest of the group stayed the same. This is not necessarily consistent with the quantitative findings in chapter 5, for some their perception as noted in the interviews matches the quantitative data, but for others there is a mismatch. Some participants perceive their improvement to be greater than their quantitative data reports and others do not perceive the same improvements as seen in their data. This is in line with recent literature (van Delden, Peper, Beek, & Kwakkel, 2013) and will be discussed further in the discussion Chapter 7.

6.3.1.2 *There is a mix of participants who are actively still trying, hope for further improvement and perceive they are improving. There are those who are not improving and or trying and conflict exists for others*

There is a mixture of feelings expressed about their recoveries by the participants and how they feel about their upper limb. Some are actively trying to improve (participants 51, 55, 58). Expressed succinctly by participant 51;

“I want to improve” (51; line 70)

This is reflected in themes identified by Barker et al (2005) of ‘keeping the door open’ For participant 55 she sums it up as;

“Oh to try and get better” (55; line 346)

and ‘continuing along in life hoping for and working towards improvement’ (Barker & Brauer, 2005).

At the time of interview, it was 5 years since participant 58 had had his stroke and when asked if he feels if he continues to improve he replies;

“In certain ways, yeah.” (58; line 48)

He has some conflict between his own beliefs, and the outcome of a recent review and some sessions with a physiotherapist with the aim of improving his walking.

“Well I was hoping to improve me walking really but it would appear I might have got as good as I am likely to be, but you never know. I do say I don’t agree with this time, people telling you don’t improve after two years of a stroke but I never agreed with that, cos I believe with advancing a bit more feeling in your leg possibly and practice at doing the walking, you do improve.” (58; line 39-44)

This gentleman has an extremely positive attitude, which drives him as will be discussed in organising theme 6.3.2. His feelings are reflected in Graven et al’s (2013) findings of focus groups of stroke survivors that “maintaining hope that functioning will improve over time was an important element of recovery” (Graven et al., 2013). Participant 44 had his stroke 15 years ago and reports;

“...we tried, we tried and we tried again...can’t do it”. (44; line 117)

He reports acceptance now related to his religious beliefs;

“As a person the only thing God has given me a less hand, do that with your left hand and forget about the right hand”. (44; lines 110-1)

Participant 51 felt he continued to improve, and appears aware of a ‘plateau’ that is discussed in relation to stroke recovery, despite recent literature to challenge it (see section 2.2.2), this quote also exemplifies his sense of responsibility for his own recovery and progress;

“I haven’t plateaued as yet, there are always things I can do...” (51; line 107)

Participant 42 appeared in some conflict, as when asked how he feels about his upper limb he replies;

“...I have discarded hope that it will come back and that’s hasn’t made life not easier but every situation easier, although now I must say that having been with my Grandchild I have an extra impulse to possibly say well maybe I should give it another try...”. (42; line 50-54)

In the same sentence he talks about discarding hope and another try, it represents some of the many emotions that people with stroke go through at all stages since their stroke. This relates to Barker et al (2005) who found their participants believed recovery only came to an end if the stroke survivor ‘gave up (Barker & Brauer, 2005). Hope is an important construct in the literature in relation to recovery, and can potentially have an important impact on their ongoing recovery (Barker & Brauer, 2005; Graven et al., 2013; Jones et al., 2008).

There was a mix of participants, some of whom were still hopeful of further improvement and were actively working towards this, and others who were not, or were in conflict; yet all committed to two upper limb research studies, involving an intervention of twelve weeks. For some participants it highlights the determination to

seek out alternatives such as research studies in response to lack of input for PwS in the chronic phase, for others it could be interpreted as still holding out some hope of change.

6.3.2 Organising Theme – Personal Attitudes, Beliefs and Approaches Are Important Factors in Upper Limb Stroke Recovery

This theme was evident in all of the other themes and is perceived by the participants as an incredibly important factor in not only their upper limb recovery, but recovery in general. The process of organizing the codes, issues discussed and basic themes that emerged in this organizing theme are detailed (Table 6.6).

Codes	Issues Discussed	Basic Themes
Attitudes Positive	Keep going Keep trying Try, try and try again Positive Keep smiling Cheerful Optimistic Determined Never saying no or I can't Attitude is part of you are Attitude is related to progress	Some participants' interviews were characterized by their positive attitude and approach to upper limb stroke recovery and life after a stroke
Beliefs Hope Religion Support	Still has hope of further recovery Has given up hope/ stopped trying (relates to recovery status organizing theme) Strong religious beliefs Support is really important	
Approaches	Get on with it and life Constantly learning how to live after a stroke Adaptability Practice and exercise are really important Use strategy of reflection on progress to self-motivate Being active Using the upper limb as much as you can Do as much as you can Try to be as independent as possible Problem solving approach Rehabilitation is a partnership between the individual and their therapist Never say no There is achievement still in doing things a different way Individuals are very much responsible for their own progress	Individuals take responsibility for their own progress/ driving their own rehabilitation

Table 6.6 Organising theme - personal attitudes, approached and beliefs are important aspects of recovery

6.3.2.1 Basic Theme – Some participants’ interviews were characterized by their positive attitude and approach to upper limb stroke recovery

When a participant had a positive attitude it was clearly evident in the interview. The optimism, positive attitudes and approaches, discussed in the interviews emerged as one of the key factors in dealing with the stroke, and approaching their upper limb recovery. In the case of participant 58, he displayed a remarkable attitude throughout his interview, with the help of humour along the way;

“... I have a positive attitude (it sounds very good that) to it. I can very easily say that with the negative attitude I wouldn’t have improved as much... I’m optimistic about the future, you know”. (58; lines 50-58)

When asked if he thought he would have been in the same position without his attitude he replies;

“I couldn’t see it, quite definitely”. (58; line 63)

He goes on to report part of his attitude and approach was;

“...being as active as possible and not just saying I can’t do it and not trying... I think I’ve got a bit more flexible and adaptable”. (58; lines 71-2,83)

Adaptability was one of his key phrases and at one point he laughed as he realized he had mentioned it a few times. He reported he kept hold of the hope that he will still continue to improve. He went on to say;

“...I understand why, yeah. I can say this is where depression comes in. if you haven’t got a cheerful of a more light-hearted view of things it would affect you in attempting anything”. (58; lines 119-21)

Participant 55 also emanated a very positive and determined attitude. She gave an example along with her humour;

“...they got me a stair lift when I came out... I soon got rid of that! A stair lift is ok but I think you are better, the phrase “use it loose it” so I thought you have to walk up and down the stairs and that’s it. I’m a hard taskmaster”. (55; lines 366-71)

She described her attitude and approach as;

“cheerful and positive...to try to get better”. (55; lines 94,346)

Her advice would be to do as much as possible and to keep trying. Participant 54 also cited his attitude as;

“...try, try and try again”. (54; line 170)

Participant 55 also agreed with participant 58 that she feels her attitude is linked to her progress so far. (55; lines 372-381). Participant 51 referred to his attitude in a definite way;

“My attitude is who I am, I can’t be doing too badly can I?”. (51; line 68)

When asked to sum up his attitude/approach it was as simple as;

“I want to improve” (51; line 70)

Jones et al (2008) also found that optimism as a feature of personality assisted their participants with dealing with stroke (Jones et al., 2008). Participant 51 also uses a strategy of self-reflection to measure his progress, which he reports as ‘unbelievable’. He believes practice and exercise are important as does participant 55, both of who are come across as highly motivated individuals. Participant 41 also came across to the interviewer as motivated and when discussed she highlighted the difficulties of trying to do exercises at home on your own and the difficulties self-motivating, as she discussed the difficult balance of physical and psychological ability and their interaction on each other.

One gentleman (participant 44) discussed his strong religious beliefs having a significant impact on dealing with his stroke, as he reported his religion, an attitude of

keep smiling and the support from his family especially his wife as the most important factors for him:

“As a person the only thing is God has given me a less hand, do that with your left hand and forget about the right hand”. (44; lines 110-111)

6.3.2.2 Individuals take responsibility and credit for their own progress

Various participants demonstrated through their attitudes and approaches that they were taking responsibility for their own rehabilitation (41, 43, 52, 55, 58). Some participants referred to their approaches as their way of dealing with having a stroke;

“...you have to get on with life don’t you?...just get with it and try and use it (her affected arm) and when I can’t just use the other one (her less affected arm)”. (41; line 53, 59)

Participant 43 talked about getting used to the upper limb not working but positively and constantly learning how to live life after a stroke and be independent;

“There are different ways, you have to do things different ways but you are always looking for answers... you have to just keep going, to see if you can find anything that makes things easy you know...”. (43; lines 57-61)

Participant 55 recalled an incident when she was an inpatient directly after her stroke which characterized her attitude and work ethic relating to her recovery;

“Lying on the bed when I first got my stroke and realizing I couldn’t move my right leg and I remember waking up about 4.30am and all morning in the bed I was trying to lift my foot off the bed and I eventually got it off”. (55; lines 348-351).

When she was asked if she thought things would have been different if she had not have had the kind of approach that she does she replied;

“I think you would be left there”. (55; line 360)

When asked if she thought she would have had the movement she has now she replied;

“I don’t think so”. (55; line 363)

She was subtly giving herself credit for actively driving her recovery. Participant 41 was more reluctant to apportion credit for her recovery;

“So the progress really is what I have been able to do with it and it has been gradual and slow...”. (41; lines 111-113)

Another participant 51 is clear about why he has progressed, when asked if his arm had improved, stayed the same or got worse in the last year he replied;

“...it’s improved, definitely improved”. (51; line 37)

When asked why he thinks it has improved he said;

“Because I work on it”. (51; line 39)

This aligns with the literature as Barker notes that those who perceived they had recovered well were more to have hope, confidence and a sense of responsibility for driving their own recovery, and the extent of their upper limb recovery will dependent on their level of commitment (Barker et al., 2007).

6.3.3 Organising Theme - Education is important

This organizing theme developed as the participants spoke about their experiences since their stroke and was a strong and important theme that runs through the interviews. The process of organizing the codes, issues discussed and basic themes that emerged in this organizing theme is detailed in Table 6.7.

Codes	Issues Discussed	Basic Themes
Information Sources of information Useful information Lack of information Quality of information Knowledge/ understanding of recovery process and timescales Good insight into rehabilitation	From the study From local stroke groups Since discharge from services From physiotherapists/ therapists Useful information can have a direct impact (advice from the study) Lack of information on discharge to be able to carry on with independent rehabilitation Lack of information as an inpatient, would have liked more to be able to understand stroke Lack of information on how to contact services in the future Information not specific enough Information given was not clear Shows awareness of neuroplasticity Relearning not learning Good level of knowledge evident Demonstrated poor level of knowledge of recovery potential and processes Time scales – improvement only to 2 years post stroke, some believe, some don't Uncertainty of timescales for recovery Lack of knowledge was disempowering – in a meeting about her future Demonstrates good insight into rehabilitation Able to adapt and progress own rehabilitation Good insight into own progress made over time Upper limb rehabilitation is complex	Information is available from a variety of sources and is valued by participants Participant's perceived a lack of information across all time points, this information can have a negative impact on an individual's ability to drive their own recovery There is varied knowledge and understanding of recovery processes and timescales of stroke recovery Some participants showed insight into the rehabilitation process and their own progress

Table 6.7 Organising theme - education is important

6.3.3.1 Basic Theme - Some participants showed insight into the rehabilitation process and their own progress

Around half of the participants directly demonstrated some insight into stroke and rehabilitation during their interviews. Participant 41 displayed insight into rehabilitation when she made the comment;

“...my arm would not work and that affects your balance and everything doesn't it?” (41; lines 87-88)

Also when discussing practicing exercises with her therapist;

“...Physios, they go over and over the same thing because that's what makes your arm go” (41; lines 167-8)

She demonstrated some insight into principles underpinning rehabilitation such as repetitive task practice and the influence the upper limb can have on gait. Participant 51 talked specifically about how he worked on strength training in his upper limb and made progress. He was aware he needed to also do specific fine motor control work to try to improve his ability to write, it seems all of which he has done with self-directed independent rehabilitation (51; lines 54-63). He demonstrated some insight into neuroplasticity when discussing recovery time scales and writing as he comments;

“it's not learning, I could always write, it's relearning isn't it?” (51; line 102)

In discussing the issues he faced with lack of sensation in his affected upper limb and compensating for this with his sight, participant 58 showed insight into the complexity of the upper limb and so its recovery;

“...it's like being able to see, see what you are doing when you haven't got feeling...or the same feeling in the right hand in my case, you learn or it brings it home to you how your co-ordination, sight and feeling are all combined” (58; lines 167-173)

Some of the participants demonstrated an impressive insight into their own recovery and the progression they have made in their own self-evaluation;

“...I remember trying just after my stroke when I couldn't spell the alphabet thing, I couldn't walk and my hand used to fall off and I had to pick it up again so I'm remembering that, and what I can do now and that allows me to know I'm improving” (51; lines 79-82)

Participant 55 also demonstrated insight into her level of recovery by reflection on her improvement (55; lines 163-7).

6.3.3.2 Basic Theme - There is varied knowledge and understanding of recovery processes and timescales of recovery post stroke

Some of the participants displayed a good level of knowledge and understanding and insight into stroke and rehabilitation when they were interviewed (41, 51, 55, 58), as discussed above. However, this was not true at all stages in their recovery. Participant 55 talks about her level of knowledge and amount of information given when she was an in-patient after she had her stroke;

“...I knew nothing about strokes or rehabilitation...”. (55; lines 184-5)

She goes on to talk about it further in the interview, when asked whether she felt her knowledge about stroke, rehabilitation and her body has changes over time she replied;

“Absolutely. I wish I had known something about stroke before I had my stroke.” (55; lines 260-1)

She felt her experience whilst she was an in-patient, which she talks about as a negative one, would have been different if she had had more knowledge and more information given at the time. When I asked her what kind of information she would like she responded she would have liked more information about everything, her lack of information and knowledge disempowered her;

“Because I mean I would have liked to have seen the scan of my brain and to be told what they found, I was never told that and I remember there was a meeting and my family came and we had some of the Medics, the sister and 3,4 or 5 could be lined up but then they were the experts, I didn’t know what questions to ask them. I didn’t know anything about a stroke...”. (55; lines 291-96)

The interviews illuminated the variety to which the participants understood current thinking or their knowledge on the current evidence regarding recovery in stroke and the concept of neuroplasticity, specifically around how long recovery can continue for after a stroke. Participant 43 stated the following;

“...my brain has been killed ain’t it that works the arm, so there is nothing going to happen now to that”. (43; lines 37-8)

Sometimes with conditions like stroke there can be common misconceptions or hearsay and some people tend to take them as hard fact. Three of the participants commented in their interview on some of the commonly discussed issues around timescales of recovery. Recovery up to 6 months is a commonly discussed timescale in relation recovery after stroke, as discussed in the literature review (see section 2.2.2). However, some of the participants refer to a two-year timeframe. Participant 51 talked about this;

“...they say the first two years don’t they, after that it’s not as easy, they used to say 6 months but I heard 2 years.” (51; lines 91-92)

He described it as hearsay ‘I heard 2 years’. The interview went onto to discuss it in relation to neuroplasticity, which he showed a good insight to, as highlighted above. This gentleman was still within 2 years of having a stroke, with the belief he held that he would be able to recover up to two years then the recovery pace would slow down. It would have been really interesting to find out how his recovery was going and his views in another year. He did state that he felt he had not plateaued yet as we discussed some patients plateau then continue to make changes, but maybe not constantly. It was also participant 51 who demonstrated a wider health knowledge as he talked about doing weight training to combat the side effects of statins.

Reed et al (2010) in a qualitative study of a community-based exercise and education scheme found the education sessions to be mainly beneficial to the people with stroke as “knowledge acquisition can be a means of regaining control over life by making sense of what has happened, understanding the implications and learning how to manage effects... knowledge that helps stroke survivors make decisions about recovery, health and living is most effective”p24 (Reed, Harrington, Duggan, & Wood, 2010).

6.3.3.3 Basic Theme- Information is available from a variety of sources and is valued by participants

There were various sources of information referred to by participants in the interviews. Two of the participants (38, 43) commented that they had gained information from the study, and two (42, 51) had kept and used the exercise sheets they were given. This shows the exercises were of value to these participants, most of which had not had any therapy contact in the previous year (see section 6.5). Other sources were the medical and therapy staff throughout their involvement with the NHS and private therapists. As mentioned earlier peer support can be a source of information. A local stroke group was a valuable source of help in adapting to find new ways of being independent for participant 43, he talked about a tip he picked up;

“...that came along after the newsletter”, so someone had obviously said like get dry with a towel and get a decent dressing gown, so I’ve got one of those now’ (43; line 66-68)

As previously discussed (Basic theme 6.2.2.1), participant 38 and her husband reported the information and advice they received in the Physiotherapist in the REAcH study had a positive impact on how much she was using her arm.

6.3.3.4 Basic Theme - Participant’s perceived a lack of information across all time points, this information can lack quality and have a negative impact on an individual’s ability to drive their own recovery

As referred to above with participant 55, some of those interviewed felt there was a lack of information to assist their knowledge and recovery. Participant 55 felt this was apparent as an in-patient. Participant 41, when asked if she felt she had much advice on how to progress once she had been discharged from the therapy team said “no” (41; line 117). She refers more than once to having to get on with it yourself without the information and support of the therapists when she was discharged;

“...thank you and goodbye, get on with it...” (41; lines 195-6)

Eng et al (2014) found from inpatient interviews, that carers felt it was a fundamental role of the clinical staff to equip the stroke survivor with the knowledge and

information to continue independently outside of therapy (Eng, Brauer, Kuys, Lord, & Hayward, 2014). This study found that PwS described ‘not knowing’ to be a key hindrance and limiting to their ability to drive their own rehabilitation. Further, in a systematic review of stroke survivor’s experiences Luker et al (2015) noted participants especially wanted information to help them to understand stroke recovery and the rehabilitation process itself (Luker et al., 2015).

The participants had varied experiences of information provision about local services and how they might be able to access therapy services or a review. When asked about this participant, 41 as discussed above felt it was ‘thank you and goodbye’, she was left alone with little help. Only when she was having recurrent falls did she see a therapist again, but only to address the falling, and she did not get to work on her upper limb with the therapist. Participant 58 had a different experience however, and in between being in the REAcH study and the 12 month follow up as part of this thesis he had investigated FES for the lower limb and had also had some sessions with a NHS physiotherapist (who was one of the Physiotherapists he had seen in the past);

“... we had been in touch at different times in that 5 years...” (58; lines 28-29)

It appears that he had had some contact with the therapy team at various times since his stroke and was able to get back in touch with them, and was aware of how to do so and that he could. By contrast, it would appear participant 41 may have been led to believe there was not an open door to being reviewed, or having any further therapy. It is difficult to know exactly the reason for his belief without questioning further. However, the Sentinel Stroke National Audit programme (SSNAP) report ‘How good is stroke care?’ highlights the differences in stroke care across the UK (Royal College of Physicians, 2014a).

6.3.4 Organising Theme - A variety of internal factors are perceived by the participants to contribute and provide challenges to their recovery

A wide variety of internal factors that contribute to, or challenge recovery were cited by the participants, a finding which is consistent with other literature (Jones et al., 2008; Reed et al., 2010). Most participants in the study discussed various factors in relation to the barriers and challenges to their recovery, which were intertwined with

their attitudes, beliefs and approaches and so strongly relate to that theme (see section 6.3.2). Some participants reported no barriers when asked (43, 44, 51).

The process of organizing the codes, issues discussed and basic themes that emerged in this organizing theme is detailed in table 6.8

Codes	Issues Discussed	Basic Themes
Contributing factors Regular exercises Regular practice Use it Move it Functional use General exercise General health	Doing exercises works Use it as much as you can ‘Use it or lose it’ agreement with this and experience of it Keep fit classes, circuits, walking, swimming, bike riding (outdoors and static), gardening, Yoga, strength training, gym	‘Use it or lose it’ is a phenomenon recognized and experienced by the participant’s Maintaining general fitness and health is perceived as important to the participant’s and contributes to their recovery
Challenging factors Physical issues	Comorbidities Decreased sensation – not my hand Feeling the cold Using the affected UL is not automatic, it takes conscious thought and effort The arm is slow, so compensate and use the other arm	Physical effects from stroke and comorbidities can be challenges to recovery
Exercising at home – independently Motivation	Exercises are hard, painful, dull and tedious Hard to motivate self on own at home	Independent rehabilitation and self-motivation can be difficult for some participants
Fear of injury Fear of participation	Fear of injury when doing prescribed exercises Fear of issues related to community activities – swimming and returning to previously valued activities – rugby Fear as inpatient – vulnerable	The participants have experienced a range of emotions since having a stroke
Anger	Anger at the hand, the situation, at their experience Anger early after stroke	
Guilt	Not doing enough to help self Not using the upper limb enough Not doing what they think they should be doing	
Blame	Calls self ‘lazy’ blames self for not doing enough / progressing	

Frustration Annoyance	<p>Perceives as her fault for concentrating on walking in the acute phase Upper limb too slow when trying to use it Recovery too slow Everything takes longer Frustration with the device</p> <p>Annoyed with recovery, not enough Fear/ worry related/ due to their impairment</p>	
Getting out Previously valued social activities	<p>Getting out and about Returning to watch rugby Returning to choir</p>	<p>Participation in the community and returning to valued social activities is meaningful and a sign of progress to participant's</p>
Support – family and friends peers professionals	<p>Balance of support and encouragement from friends and family Attitude of others is influential Support from others in a similar position or similar experience Support, advice, encouragement and motivation from professionals (in and out of groups) Physiotherapist is like a personal trainer Psychology support from the start would be good</p>	<p>Participants draw on support from a variety of sources</p>
Groups	<p>Companionship, motivation, inspiration, social Influence of a positive attitude on others Get to see a therapist Support from therapist of advice, expertise Security of an appointment</p>	<p>Groups were reported as having social, psychological and physical benefits</p>
Therapy Physiotherapy	<p>Physiotherapy is important in recovery More physiotherapy Amount of therapy Positive attitudes of therapists NHS therapy and private therapy Seeing a therapist at a group is valued</p>	<p>Any input from therapists is valued by the participants</p>

Table 6.8 Organising theme - a variety of internal factors are perceived by the participants to contribute and provide challenges to their recovery

6.3.4.1 Basic Theme- ‘Use it or lose it’ is a phenomenon recognized and experienced by the participants.

A common theme amongst most of the participants was that of ‘using’ their upper limb to aid their recovery (**41**; line 46, **43**; line 31, **51**; line 48, **58**; line 109), this included advocating using it functionally (**38**; line 154, **41**; line 46, **55**; line 77, **58**; line 109). Participant 41 reports;

*“Just trying to use it as much as you can”. (**41**; line 46)*

This reflects previous qualitative studies where ‘use the arm in everyday tasks’ was independently responsible for more than 12% of the variance in recovery (Barker et al., 2007). In line with this attitude of functional use, three participants agreed with the common phrase known in rehabilitation of ‘use it or lose it’ (Hidaka, Han, Wolf, Winstein, & Schweighofer, 2012). Participant 41 when asked if she had some experience of use it or lose it, she responded;

*“definitely yeah...quite right, if you don’t it would just hang and not be able to use it at all”. (**41**; lines 70,75)*

Participant 55 agreed and described how she is;

*“...very conscious of the use it or lose it...My view is you definitely should use it, if you don’t you lose it”. (**55**; lines 85,87)*

Participants 41 and 44 agreed that doing exercises does help the upper limb and works and participant 41 highlighted the use it or lose it principle;

*“It (her upper limb) improved with the exercises and whilst I was doing it all the time on a regular basis, but I would say that it has gone slightly backwards because I am not exercising it all the time”. (**41**; lines 15-17)*

6.3.4.2 Basic Theme- Maintaining general health and fitness is perceived as important to the participants and contributes to their recovery.

Most participants noted that they undertook some form of general exercise regularly which they felt benefitted them and their recovery. These activities range from group activities such as circuits and keep fit activities, to individual pursuits such as swimming, yoga, walking and bike riding. Participant 42 specifically feels that for him swimming is;

“a bit more holistic and the arm movement has actually improved...it affects my shoulder and posture”. (42; lines 68-9,73)

After a stroke physical activity and fitness levels are known to be low and this can be associated with limitations in activity (Nicholson et al., 2014). Regular physical activity can not only improve fitness, but functioning and health and wellbeing after a stroke. It can lead to improved walking speeds, walking capacity, functional mobility, muscle strength, bone density, quality of life and can reduce further the risk of another stroke (J. H. Morris, Oliver, Kroll, Joice, & Williams, 2015). Most of the participants reported taking part in regular exercise, which can be a difficult after a stroke given the barriers, such as transport issues, lack of skill, poor self-efficacy, beliefs about capabilities, social influences and memory and attention deficits (Nicholson et al., 2014). A deconditioned state of fitness can compound impairments resulting in further activity limitation and participation (J. H. Morris et al., 2015). Participant 51 in particular was motivated to do general exercise as;

“I enjoyed the exercise and it does me good”. (51; line 14)

He was attending a keep fit class run locally by Physiotherapists but stopped going as it was poorly organized. However, he appears highly self-motivated and plans to join a gym as an alternative. He also demonstrated a good knowledge of his general health and wellbeing and takes active steps to maintain his health. He reports doing strength training;

“...because I take some statins they encourage muscle wastage don’t they? So I’m combatting that and building up my strength in my hands”. (51; lines 114-6)

6.3.4.3 Basic Theme - Physical effects from stroke and comorbidities can be challenges to recovery

Some of the physical factors cited by the participants were issues such as comorbidities such as carpal tunnel syndrome in the affected upper limb affecting their abilities with the arm (41) and feeling the cold more since the stroke (42). Two volunteers (38, 58) discussed the issues related to decreased sensation, which has an impact on their function and abilities to engage in tasks. Participant 38 reported that;

“It’s not my hand” (38; line 16)

The researcher sought to qualify the statement by asking if it felt like it belonged to her, to which she replied “No”. This is reflected in a thematic synthesis of qualitative studies looking at patient’s views on the impact of stroke on their roles and self by Satink et al (2013), who noted that patients experienced a split or discontinuity in the connection between their body and their self, with several parts of their body feeling alien (Satink et al., 2013).

Participant 58 described the feelings he has regarding the sensation problems he faces with his affected arm;

“... screwing nuts and bolts together...it’s all combined, it’s like being able to see, see what you are doing when you haven’t got feeling.” (58; lines 166-169)

The reduced sensation had forced him to rely on his sight more and adapt the way he approached tasks, despite his sensation being a hindrance to his UL recovery his attitude of adapting and trying carries him through to overcome these barriers, with the additional assistance of attending the Men in Sheds group (see section 6.3.5.3). Three of the participants talk about the issue that their affected arm does not join in automatically with activities and have to make a more conscious effort to use it (38; lines 169-72, 41; line 61 and 58; line 211);

“... I mean I’ve been doing it for 60 odd years being two handed and all at once to not have a hand that is as useful. I wouldn’t say I am not without it but obviously it’s not as helpful”. (58; lines 213-7)

When asked if she tries to use it as much as possible replied;

“Yeah but not enough. I do try and use it as much as possible when I remember not to let my left one take over, you automatically take over with the left one.” (41; lines 61-3)

This lack of automaticity may contribute to the cycle of learned non-use, in which through non-use the limb decreases in strength and ability, and so in turn becomes less functional, thereby further reducing the tendency to use the limb.

6.3.4.4 Basic Theme - Independent rehabilitation and self-motivation can be difficult for some participants

Participant 41 referred to a variety of challenges she faced once she was home and in trying to continue her rehabilitation and do exercise at home, which she describes as “hard” and when referring to the therapists who were seeing her at home;

“...they don’t realize how hard it is to motivate yourself to do it, but when you have got... (refers to the Physiotherapist) it’s like having a personal trainer isn’t it?”. (41; lines 153-4)

When we went on to discuss it more, as the interviewer, I commented that she came across as a very motivated person and she replied;

“Yeah but when only half of you are working it is very difficult. It is not the motivation, it’s to physically be able to do it. Your head wants to do it but your body is not doing it, you can do yourself an injury.” (41; lines 172-4)

In this quote, she is separating motivation from the physical ability and identifies her body as the barrier to rehabilitation, due to the fear of injury. Another challenge for participant 41 was that exercising on her own at home was difficult as;

“...it can get tedious.” (41; line 20)

There are various rehabilitation technologies such as gaming, which could potentially assist in improving the patient's experiences, making their rehab challenging, motivational and interesting at the same time. There are also developments in virtual reality that can be used as a stand-alone therapy intervention, or in combination with other technologies such as FES (Laver et al., 2011).

6.3.4.5 Basic Theme – The participants have experienced a range of emotions since having a stroke

A range of emotions ran through the interviews. Fear can limit people with stroke from participation, and doing previously valued activities, such as in the case of participant 41, swimming;

“I was so frightened of slipping, you know going on my own or with a friend, I was frightened of slipping, let alone drowning with only one hand but my legs not working properly, you can't wear an ankle brace”. (41; lines 184-6)

Attending rugby matches for participant 43 evoked fears of crowds;

“...when you first start off with this no balance and that you are quite terrified of being in a crowd...”. (43; lines 52-53)

Participant 41 goes on to talk about her frustration;

“Why can't I do what I used to be able to do with it, it's annoying, it's very frustrating and things aren't precise, it's clumsy” (41; lines 65-67)

The feelings she talks about such as annoyance and frustration reflect what a complex situation it is for someone after a stroke (Alaszewski, Alaszewski, & Potter, 2004). She refers to these feelings of guilt and not doing as much as she should, so I asked her ‘but not enough according to who... to you?’ she replied;

“There is only me really isn't there? Why can't I do what I used to be able to do with it, it's annoying, it's very frustrating and things aren't as precise, it's clumsy”. (41; lines 65-7)

Here she is expressing her annoyance and frustration with her upper limb, and goes on to get a little teary when she states;

“...it is not fast enough and I have not recovered enough”. (41; line 77)

This echoes results from the focus groups of Graven et al (2013), who found the majority of stroke survivors tended to express feelings of frustration around their slow rate of recovery (Graven et al., 2013). It appears that, whatever anyone else’s opinion, participant 41 feels she has not recovered enough and has a variety of emotions regarding it. The finding also relates to previous reports of PwS feeling their body to be unreliable (Satink et al., 2013). Satink (2013) also highlighted how, persons with stroke can feel uncomfortable in environments outside the home, where they feel less able to control their bodies.

6.3.5 Organising Theme – A variety of external issues are perceived by the participants to contribute and provide challenges to their recovery

A stroke is a life-changing event that has an impact not only on the person but those around them. External factors can make positive contributions to recovery, but may also provide challenges.

The process of organizing the codes, issues discussed and basic themes that emerged in this organizing theme is detailed in table 6.9.

Code	Issues Discussed	Basic Themes
Contributing Factors Getting out Previously valued social activities Support – family and friends peers professionals Groups Therapy Physiotherapy Challenging Factors Not enough physiotherapy/therapy as inpatient and at home Staff Attitudes of professionals	Getting out and about Returning to watch rugby Returning to choir Balance of support and encouragement from friends and family Attitude of others is influential Support from others in a similar position or similar experience Support, advice, encouragement and motivation from professionals (in and out of groups) Physiotherapist is like a personal trainer Psychology support from the start would be good Companionship, motivation, inspiration, social Influence of a positive attitude on others Get to see a therapist Support from therapist of advice, expertise Security of an appointment Physiotherapy is important in recovery More physiotherapy Amount of therapy Positive attitudes of therapists NHS therapy and private therapy Seeing a therapist at a group is valued Not enough input as an inpatient Not enough when at home Acute – focus on mobility and transfers not the upper limb Low level of input with upper limb (including those severely affected) Poor/ negative staff attitudes/ behavior caused upset Staff unfriendly Upset by the way staff spoke Felt disempowered due to lack of knowledge in a meeting about her future Felt vulnerable Lack of autonomy Afraid to speak up with concerns/ feelings Had a number of private physiotherapists who she felt were not interested in her recovery Rehabilitation is a partnership between the PwS and the therapist Saw different therapists – confusing	Participation in the community and returning to valued social activities is meaningful and a sign of progress to participant's Participants draw on support from a variety of sources Groups were reported as having social, psychological and physical benefits Any input from therapists is valued by the participants Some participant's perception is they did not receive enough therapy across all the time points Staff behavior and attitudes can negatively affect individuals

Environment	Did not go to a stroke specialist ward Stayed in the room all the time	Some participant's had negative experiences in relation to the services they received
Discharge from NHS services	On discharge from services had little or no active movement, has improved on own since Feels of being left to 'Do it yourself' (DIY) Made to feel you are on your own No advice on discharge of how to self-manage/ progress Got to a certain level then they just stopped coming- feelings of abandonment	
NHS Resources Funding The system UK/ Germany	Upper limb group was beneficial but stopped Balance group was beneficial but stopped Feels lack of funding is why she did not receive the therapy she deserved The system is wrong 'Same old story' issues with the system/ organization implies not a new issue or an isolated one Feels there is better care now, than they received Feels might have had better care if had been in Germany (country of origin)	

Table 6.9 Organising theme - a variety of external factors are perceived by the participants to contribute and provide challenges to their recovery

6.3.5.1 Basic Theme – Participation in the community and returning to previously valued activities is meaningful to the participants

Participant 43 believed exercising by getting out and walking everyday helped his overall recovery, especially his balance, which has led to greater participation and resumption of a previously valued activity, attending rugby matches. As part of the disparity that can exist between stroke survivor's and health professional's perspectives of recovery, stroke survivors view recovery not just in terms of physical improvements (Graven et al., 2013). Graven et al (2013) found, in their focus group studies of stroke survivors, carers and health professionals, that returning to previously valued activities was commonly used as a benchmark for defining, or measuring recovery, by both stroke survivors and carers. Participant 43 illustrates this point;

“...I have actually been watching rugby this year cos when you very first start off with this no balance and that you are quite terrified of being in a crowd, so I could come to terms with it you know?”. (43; lines 51-4)

Participant 58 also went back to a previously valued activity of attending a male voice choir, which benefits him in various ways;

“...going to the male voice choir has helped me speech a lot... the social side is very good as it really brings home to yourself the different attitudes of people, and I do feel that you begin to realize the difference between close friends and acquaintances...” (58; lines 257-8, 268-9)

6.3.5.2 Basic Theme – Participants draw on support from a variety of sources

Sources of external support were highlighted by most of the participants. These included professional staff, peer support and support from family, partners and friends. Peer support has been discussed in the basic theme related to groups (see section 6.3.5.3). Participant 42 reported he received just the right level of support from his partner at the time who was;

“...relatively supportive but not overpowering you know ...basically she let me get on with it, if she thought I could do it, she would never come to help me because she thought get on with it yourself”. (42: lines 136-140)

The ‘right level’ of support can be a balancing act and is important as “...paternalism of health care providers and family members, and over protectionism of family were recognized as a barrier to regaining autonomy and becoming active” (Satink et al., 2013). Support from partners, relatives and friends are well recognized in the literature as a key factor to support the person with stroke (Barker & Brauer, 2005). Participant 58 also talks about the value to him of the support he has in his life;

“without the companionship and friendship of other people... in various ways, not only my wife (laughs) especially my wife sorry (laughs) it must be very difficult...his wife adds – to be motivated, ...yeah to be motivated...”. (58; lines 250-3)

He goes on to comment about his involvement in a male voice choir;

“...I do feel that you begin to realize the difference between close friends and acquaintances, and that has a big effect”. (58; lines 268-70)

Participant 44 also describes the support he received from his wife and family as very important to him and as being right for him, as he describes her as ‘pushy’ she says;

"Come on". (44; line 53)

Participant 42 highlighted he feels there should be dedicated (professional) psychological support available from admission to assist with ‘*coping with your situation*’ (42, 187). Currently, in the UK there is patchy psychological support available within stroke units, with only 61% of services having access to a clinical psychologist (Royal College of Physicians, 2014b).

6.3.5.3 Basic Theme – Groups were reported as having social, psychological and physical benefits

Doing an activity as part of a group can be beneficial, as expressed by participant’s 42 and 58 with a lot of enthusiasm. Participant 58 describes attending a group called ‘Men in Sheds’ and reported how being involved has helped him reaffirm his approach of trying and not saying ‘I can’t’. He describes below what the group is about:

“Men in Sheds is a gang of men (laughs) but in a nice sort of way! with all sorts of disabilities, not necessarily all physical and its companionship in a lot of ways, being with men with similar problems, coming together for a few hours and having the attitude to try things rather than just say you can’t do them”. (58; lines 89-93)

He found benefit from a group environment and the peer support, which he has found motivational, inspirational, supportive and helpful to his journey after his stroke. This gentleman talks often in his interview about adaptability, which he deems to be very important, to have the attitude to try new things. When he was asked whether he feels he benefits from the group he replied;

“Oh yeah definitely...well practice makes perfect doing things, it encourages your adaptability if that’s the right word, to attempt these different things.” (58; line 108)

The group he attended was quite practical based and he had done activities such as screwing together bird boxes, this had inspired him to try more tasks at home. This is reflected in the qualitative study carried out by Reed et al (2010) who ran a community exercise and education group. The participants of their study reported that it was ‘fun’, and ‘a laugh’ and the positive attitude boosted the morale of individuals in the group. Further, it provided a means of increasing self-esteem and supporting each other in their desire to improve (Reed et al., 2010).

Participant 42 attended an upper limb group as an out-patient to an NHS hospital as part of his therapy. He was very positive about the experience and its benefits;

“...well it was good, because all the people were users of Saeboflex (an upper limb orthosis) and being in a group is always a good thing and just having that once a week, it’s just an encouragement”.
(42; lines, 103-5)

He also reported one of the benefits of a group is that of peer support. This is reflected in the study by Reed et al (2010) who found that peer support can have the multiple benefits such as a nurturing environment, where participants can learn from each other, increase confidence which fuels their continued drive for recovery, and assist with their view of their social selves (Reed et al., 2010). Participant 42 also referred to having the security and assistance of a regular appointment where he can gain support, advice, encouragement and motivation from the rehabilitation professionals in the team. In the interview he also discussed how he set targets with the assistance of the rehabilitation team, another external factor.

“...as I say it’s a good thing and I think it was quite useful because...you can set yourself targets and so on and so forth and it was a slow progress but you made progress, yeah”. (42; lines 108-111)

He also acknowledges that whilst progress might be slow, which it can be in the chronic phase, it is still progress.

6.3.5.4 Basic Theme – Input from therapists is valued by the participants

Participant 41 described seeing a physiotherapist was like having a personal trainer;

“...when you have got a (a Physiotherapist) ...it’s like having a personal trainer...”. (41; line 154)

By likening the two, she implies a physiotherapist gives her specific, personalized knowledgeable attention and information in order to assist her in her rehabilitation. Therefore, we should not underestimate the impact of therapy for people with stroke who are in the chronic phase in relation to the knowledge, advice and support given which guides independent rehabilitation. The value placed on Physiotherapy was picked up as theme in a study by Jones et al (2008) in relation to therapists providing motivation and encouragement (Jones et al., 2008). Participant 55 had been attending private physiotherapists for approximately seven years. Initially she struggled to find one with whom she felt that she had a partnership with and who invested in her improvement;

“.. you know unless the patient can feel that they have got someone who is interested and wants them to get better and that is a big input” (55; lines 233-35)

She explained that;

“with their effort and your effort you can do better” (55; lines 240-41)

She goes on to speak in glowing terms of her Physiotherapist that she sees regularly;

“...phenomenal...” (55; line 242)

“She is so passionate about her job...” (55; line 243)

“She is fantastic.” (55; line 246)

6.3.5.5 Basic Theme – Some participant’s perception is they did not receive enough therapy across all the time points

Not enough Physiotherapy input was stated by two of the participants. When participant 55 was asked about the amount of input she had with her arm at the beginning after her stroke she replied;

“not much” (55; line 133)

She went on to comment when asked about her therapy as an in-patient;

“Fairly little, when I think back now, I think I should have had (should is the wrong word) but would have liked more...” (55; lines 183-4)

When asked if she would have liked more therapy for her arm she replied;

“Oh definitely more, more, more” (55; line 140)

There is a thread throughout the interview with participant 41 regarding therapy;

“not that often... it was not for long” (41; lines 102,103)

Participant 41 links the wish for more therapy, or the wish she would have had more therapy in the past to the NHS;

“... you don’t get enough Physio, it is the same old story you don’t get enough, there isn’t enough. You need Physio every day...”. (41; lines 146-7)

“All I said you don’t get enough Physio isn’t it? The system is wrong. I want more Physio”. (41; lines 215-6)

The perceived lack of therapy input is reflected in the report ‘How good is stroke care?’ where patients and their families reported the amount of therapy received was a major concern (Royal College of Physicians, 2014a). Participant 55 discussed coming across other issues with her therapy (private);

“...they came for a while and then got fed up I think, they left for their own reasons...I did not have any one Physio who was interested in me to get better and that is very important.” (55; lines 221-4)

6.3.5.6 Basic Theme – Staff behaviour and attitudes can negatively affect individuals

Participant 55 highlighted an example of the type of staff behaviour that was discouraging to her

“...none of the staff talked to you, the Sister was very unfriendly...”.
(55; lines 305-6)

“...I was trying to get from the chair to the wheelchair and I thought you know quite successfully in as much you had to do things and I think the sister came in and told me I shouldn’t do that and I thought (I didn’t say anything at the time as you are very vulnerable, you don’t say anything do you? You just do as are told, it’s like being back at school) and that wasn’t much encouragement to me...I think it was health and safety was more her thing than the patient’s recovery”. (55; lines 329-38)

There are various issues highlighted by this quote, including the perceived unfriendly and unsupportive attitude of the staff. This is also reflected in a study by Eng et al (2014) who found that “building motivation” to drive recovery was heavily influenced by the attitudes of clinical staff, described as an external source of motivation which was not necessarily positive (Eng et al., 2014) . Eng et al (2014) also referred to the passive rehabilitation culture and the nursing and therapy staff acknowledged that they could be playing a part in reinforcing this passiveness, but also aimed to support the patient’s independence and autonomy. Luker et al (2015) noted that disempowering staff attitudes could have a strong negative influence for many. These included “authoritarian attitudes and decision- making processes, restrictions on participants’ acts of independence or access to information, and dismissive responses to participants’ goals” (Luker et al., 2015). More worryingly were participant 55’s comments about her lack of autonomy and the fact she felt she was unable to make her feelings known at the time as she was in fear of what would happen if she did.

6.3.5.7 Basic Theme – Some participants had negative experiences in relation to the services they received

Two of the participants had external barriers created in terms of the groups they were attending. For participant 51 he stopped going to his group due to its poor organization, and he sought out an alternative gym-based group. However, participant

42 was attending an NHS run group, which he attended as an outpatient at the hospital. He found it beneficial until it was stopped due to funding issues and reports this as a contributory factor to him giving up on his upper limb rehabilitation:

“...it was possibly one of the reasons why I eventually thought I would stop it altogether, I mean if the group had gone on I wouldn’t have stopped”. (42, lines 117-9)

This highlights the significant impact on people with stroke of having regular contact with health professionals and the impact of stopping services and schemes. This also serves to illuminate the diversity in the ways in which people with stroke deal with having a stroke and their recovery and rehabilitation. While participant 51 stopped going to a class voluntarily due to the poor organization, he actively sought out another and keeps up with daily walking and strength training independently. Participant 42 also attended an NHS balance group and this was also stopped due to resource issues. This participant in particular has had external barriers put up to his rehabilitation. Participant 42 comments on the NHS and its funding when he was discussing why both of the groups he attended were stopped.

“...of course eventually it folded because there was not enough money or whatever...again that was stopped because of resources problems...”. (42; lines 97-99,125-6)

Participant 41 (above) and 42 use language such as ‘same old story’ and ‘of course’ they convey they were not surprised by it and were resigned to it. Participant 42 who lives in the UK but originates from Germany went on to say;

“... it’s somehow my feeling that I would have possibly have got better support in Germany, I’m not sure, it’s not a complaint”. (42; lines 91-2)

Some of the participant’s experience of discharge from services was generally quite negative leaving, them with feelings of abandonment;

“...you got to a certain level then just didn’t turn up anymore”. (55; lines 129-30)

When participant 41 was asked about how often she saw the therapists when she was at home she commented;

“Not that often, I think it was twice a week at home and it was not for that long, it was only until I could hold my arm up and it could hold it by itself and got a bit of movement in it and they say “oh just get on with it” like they do. They go (participant does an imitation of a person saying) ‘your star team is finishing now, now you have to take over and do it yourself’”. (41; lines 102-7)

This comment aligns with Barker et al (2007) who found ‘not enough movement to work with’ was the second most important factor, representing the greatest barrier to recovery (Barker et al., 2007). Technologies such as FES have the capacity to facilitate PwS in this category to access repetitive task practice. Participant 41 also goes on to say she received very little or no information on how to manage her own rehabilitation after she was discharged, as a consequence she was left feeling abandoned and bitter about this. Again, there are comments such as ‘like they do’ implying this is the way it is despite her displeasure with it, a resignation to it.

6.4 Summary

Some of the participants were actively still hoping and working towards upper limb recovery, and achieving it despite being up to seven years post stroke. This finding adds to the body of evidence on continued recovery in chronic stroke patients and is reflected in Barker's work on the stroke survivor's perspective. Barker reported themes of ‘keeping the door open’ and a process of ‘continuing along in life hoping for and working towards improvement’ and participants in their study also emphasized the importance of not placing time limits on recovery (Barker & Brauer, 2005). The positive attitude and approach of the participants was a theme that ran throughout the interviews and characterised some of the interviews. Some of the participants have, from their own accounts, made significant recoveries, despite the severity of their stroke initially with the majority of this being after they were discharged from services. The majority of the participants were continuing with their recovery without any professional help. Education was important for the participants and a greater understanding of recovery processes could enhance their efforts. There

are factors, which contribute to assisting the participants in their recovery, and factors, which are challenges. These factors are not only physical, but are also psychological, emotional and social. The basic and organising theme 2 are illustrated in a thematic network (figure 6.2).

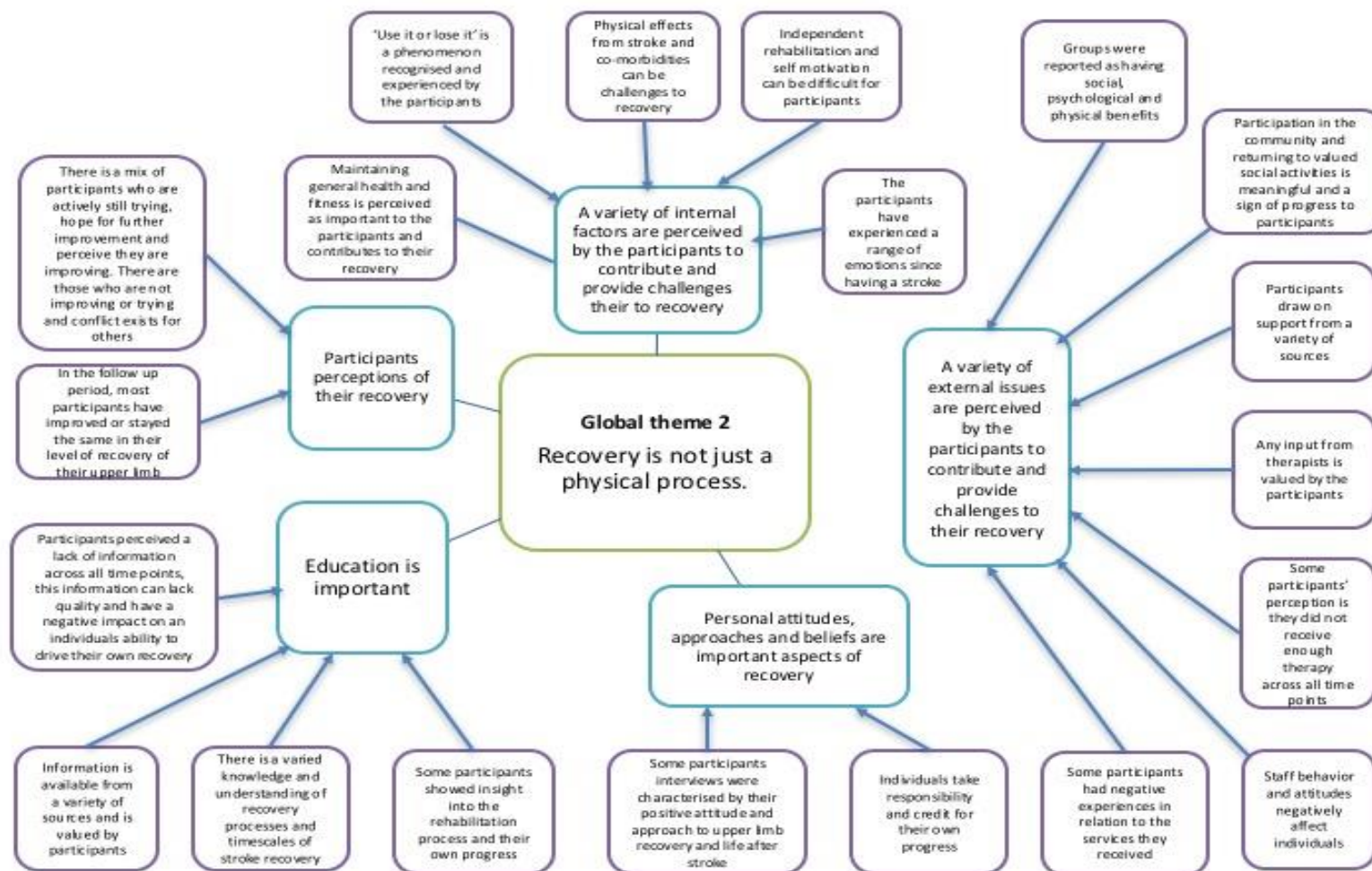


Figure 6.2 Thematic Network: Global theme

Chapter 7 Discussion, Limitations and Conclusion

This Chapter reviews the findings from the author's study in context of the available evidence base. The quantitative and qualitative findings are reviewed in relation to the study aims, along with a critical evaluation of the merits of using a mixed methods approach. Finally, the qualitative and quantitative findings are compared and contrasted and conclusions drawn.

7.1 Long Term Follow-up of FES in People with Chronic Stroke

It is currently not commonplace amongst therapy intervention studies to include a long-term follow up period to determine retention of any changes noted in the short-term (see section 2.8.9). This is despite a weight of opinion promoting the practice, in order to enable fuller evaluation of interventions (Hayward et al., 2010; Pollock et al., 2014). The author's study proposed a one year follow up, in line with one of the most notable follow up studies to date, in which retention of positive outcomes have been demonstrated at one and two years after intervention with CIMT in sub-acute and chronic stroke (Wolf et al., 2006; Wolf et al., 2008). Winstein et al 2004 also noted retention and continuation of gains in functional task practice and strength training groups over a standard care group over a 9 month follow up period (Winstein et al., 2004).

In relation to FES studies, as noted in the literature review, only 13 long-term follow-up studies have been published, and of these around half are in chronic stroke, the majority of which have carried out follow up of 3-months or less. This study aligns with only one other that has reported a follow up in voluntary triggered FES, the pilot to the REAcH study, which itself suggested a longer term follow up of 6 or 12-months would be of interest (Mann et al., 2011).

7.2 Quantitative Findings in Relation to the Research Aims

The main aim of the quantitative arm of this study was to identify whether changes in impairment, function and quality of life seen during the REAcH study were maintained at the 12 month follow up. The results of the REAcH study were not known at the time of application for this study. As only small changes were reported in the REAcH study (Appendix 2) and no significant differences were present between the intervention groups at the end of the intervention period, a pragmatic decision was made to consider the follow-up group of 9 participants (4 in the FES group and 5 in the exercise group) as one intervention group.

There were no statistically significant differences for the follow-up group in five out of the six measures following the intervention period in REAcH (table 5.5) and therefore minimal change to assess maintenance of follow-up.

Statistically significant changes were noted in two domains of the self-reported SIS, a quality of life measure concerning participation ($p = 0.003$) and overall recovery ($p = 0.0066$). There was no statistically significant difference between 12 and 64-week follow-up for either domain, however the trend was a positive one, confirming that change had at least been maintained. This change in the self-reported measures was not mirrored in the functional or impairment measures. This inconsistency between self-report and objective measures was similar to data from van Delden et al (2013) who found no statistically significant association between improvements in ARAT and SIS (Hand) over 17 weeks in 39 sub-acute PwS (van Delden et al., 2013). Dromerick also noted that self-reported measures captured information not assessed by functional limitation or impairment scales (Dromerick et al., 2006).

McKevitt et al (2004) identified that health professionals tend to consider recovery in terms of mobility and basic self-care activities, whereas PwS use premorbid level of function as a benchmark of comparison (McKevitt, Redfern, Mold, & Wolfe, 2004). Returning to previously valued activities, was commonly used as a benchmark for defining or measuring recovery by PwS (Graven et al., 2013). Authors agree that to PwS participation and social valued activities can be more meaningful than a functional score (Jones et al., 2008; Woodman, Riazi, Pereira, & Jones, 2014). This

was seen in both the quantitative results and the thematic analysis, and is perhaps the reason for the significant change in self-reported participation found over changes in function or impairment measures.

Despite not demonstrating the significant improvement seen in other follow up studies (Barker, Brauer, & Carson, 2008), both exercise and FES groups in the REAcH study and this follow up study did find small non-significant improvements. Similarly, improvements in two separate intervention groups (without difference between the groups) but not in a control group receiving no intervention, were also noted over long-term follow-up (Barker et al., 2008). The exercise group in REAcH was labelled a control group, however the participants also received an intervention, i.e. exercise and repetitive task practice, which may have resulted in the difference between groups being insufficiently distinct to identify. This underlines the significance of any therapeutic intervention in chronic stroke and the highlights the challenges with clinical intervention studies in chronic stroke.

The REAcH study did not fulfil the promise of the pilot (Mann et al., 2011). There are possible reasons for the lack of significant changes and between group differences in the REAcH study, and hence lack of change to maintain in the follow up. The pilot study lacked a control group and measures taken were by an un-blinded rater, potentially introducing bias to the outcome measure scoring. Usability and reliability problems were encountered in REAcH, which were also noted in 3 out of the 4 FES participants in this study (see section 6.2.1). Although some re-engineering of the device was undertaken between the pilot and REAcH, the device could have benefitted from further usability and reliability work. Additionally, duration of use of the device per day in REAcH was 85 minutes compared to 3 hours reported in the pilot, a marked difference, which could be due to the usability and functionality issues. Due to this and without more robust data on use and repetitions, it is difficult to draw conclusions on whether the participants as a group were able to achieve the high intensity of task practice the literature suggests may be needed to promote the neuroplastic changes (see section 2.4).

It is also possible that participants in both arms of the REAcH study may have benefitted from additional support. Recent research suggests augmenting FES with

behavioural supports can significantly reduce impairment in moderately impaired stroke (Page, Levine, & Basobas, 2016). In the Page (2016) study the behavioural supports consisted of a behaviour contract, weekly review of upper limb use, problem solving to overcome barriers to upper limb use, review of videotaped clinic sessions and structured, specific 'homework' regimes (Page et al., 2016). The dose of treatment in the Page et al (2016) study used was based on previous work by the same author, reporting 120 minutes as the optimum dose, delivered 3 days a week over 8 weeks (Page, Levin, Hermann, Dunning, & Levine, 2012). The combination of behavioural supports combats the issue of learned non-use and targets the number of repetitions needed to see changes in impairment and function. In comparison, in the REAcH study, there were only three scheduled clinic visits for review by a physiotherapist during the intervention period.

7.3 Could Changes in Outcome be Attributed to the Nature of Intervention?

Given the absence of significant difference between the exercise and FES groups in the REAcH study, and the small numbers recruited to this study, it was no longer possible to explore the second aim; whether any changes in outcome could be attributed to the nature of the intervention. Despite this, it is of note that individual improvements were made not only amongst the higher functioning participants, but also in the lowest functioning participant recruited, demonstrating the potential for change regardless of stroke severity (Appendix 7). Stratification of participants according to their severity could be beneficial in future research studies to examine recovery in the different groups.

7.4 Participants' Experiences and Perceptions of Upper Limb Recovery

7.4.1 Interventions in chronic stroke

The qualitative data cast further light on the quantitative results. In a similar way, Page et al (2016) used Motor Assessment Log (MAL) alongside F-M and Box and Block to assess FES augmented with behavioural supports (Page et al., 2016). Quotes obtained from the MAL allowed the authors to report that participants commented

upon new abilities to perform valued activities they had not been able to in months. This translation of positive changes into valued activities, a key target for upper limb interventions, was not apparent from other the measures.

Participants reported positive experiences of participation in the REAcH study and their perceptions of voluntary triggered FES were identified in global theme 1 (figure 6.1). All participants were asked if they had investigated FES in any way since their involvement in the study, only two had (see section 6.2.1). This question was designed to assess the impact of use of FES on the participants. The responses highlight the low awareness and knowledge of FES amongst the participants. This is consistent with recent literature finding that key barriers to translation of assistive technologies into clinical practice are lack of knowledge, education, awareness and access for the PwS and clinicians (Hughes et al., 2014). Participants in the author's study described the overall concept of FES as 'good' and provided feedback on the usability and functionality of the system. This highlights the importance of user involvement in technology design and development and the need to provide education to both patients and therapists on rehabilitation technologies (Hughes et al., 2011).

The majority of the participants reported that their involvement in the study had a positive impact on them, despite the group statistics not showing any difference in functional or impairment measures. One of the most significant elements was the impact on participants of review by a physiotherapist who specialises in neurology. It was seen as useful, motivational, supportive, a source of advice and education and provided a source of commitment to doing the exercises (see section 6.2.2). These were all factors illuminated during the interviews as significant in upper limb recovery. For example, participant 38 reported a direct impact on upper limb use related to interaction with the physiotherapist and the advice and education she was able to provide for the participant to use her arm more (see section 6.2.2). This participant reported greater use of her upper limb at one-year follow-up and was able to switch on lights, something she was unable to do before, despite no marked change in her functional measures.

7.4.2 Non-physical factors and their impact on recovery

The second global theme, which emerged was ‘Recovery is not just a physical process’ (figure 6.2). The interview data illuminated the individual nature of recovery and how it links to individuals’ perception of their recovery status, hope, attitude and approach, as well as their self-responsibility to drive their own recovery. This strongly aligns with the limited literature on PwS perceptions of upper limb recovery and recovery in general (Barker & Brauer, 2005; Barker et al., 2007; Graven et al., 2013; Jones et al., 2008). Each person perceived their recovery status in their own way and had differing expectations, similarly found by Graven et al (2013) where ‘individual recovery expectations’ was a main theme.

Some participants reported at follow-up that they were not actively trying to improve their upper limb (43,44), despite having enrolled in an upper limb research study just over one year previously. They reported contentment with their current functional status. This attitude aligns with Gravens’ (2013) findings where acknowledgement and acceptance of changed abilities was considered an important component of establishing new routines and generating a more positive outlook for the future (Graven et al., 2013). Some participants appeared in conflict and described ‘discarding hope’ (participant 42) and being told they are as good as they will get (participant 58), whilst still looking for change. Maintaining hope is a key element in PwS perceptions of upper limb recovery (Barker & Brauer, 2005; Barker et al., 2007; Graven et al., 2013; Jones et al., 2008).

Five participants (41, 51, 54, 55, 58) reported they were still actively trying, working and hoping for further improvement and recognised their own role in rehabilitation. MacLean et al (2000) found that many patients thought they had an active role in rehabilitation and that they had to apply effort to make gains, and only patients with low motivation thought they ought to simply wait for recovery (Maclean et al., 2000).

There were three participants whose interviews were characterized by their positive attitude and approach, which appeared to be a significant factor in their upper limb recovery (51, 55, 58). Participant 51 has an attitude of ‘keep trying’ and reports continued attempts to improve. Participant 55 has a strong sense of self-responsibility

and was very determined with a positive and cheerful attitude, her approach was also one of to 'keep trying', and she believed her attitude plays a significant part in her progress. Participant 58 was also very positive and tried to see things in a light-hearted way, reporting that adaptability was his key approach. Robison et al (2009) noted that adaptability is a key element to resuming previously valued activities (Robison et al., 2009). Participant 58 believes his positive attitude and adaptability played a key role in his progress. Van Delden found that a match between objective and subjective measures was highest in those with a positive mood (van Delden et al., 2013).

Participants found there were both internal and external factors involved in their recovery and this became an organising theme of the study. This aligns with the findings of Jones et al (2008), where participants also noted the importance of both internal and external factors (Jones et al., 2008).

Education is an external factor and is highlighted as an issue throughout the timeline of recovery. Participant 43 stood out in relation to his lack of knowledge of the recovery processes and the potential for recovery, as he reports believing there is no potential for recovery in his upper limb. He showed no changes in his objective measures. It is conceivable greater availability of information may have changed this outcome and developed greater expectation of recovery. Graven et al (2013) highlight the need for health professionals to explore PwS and their carers views "about their concepts of recovery, as greater awareness and attention may maximise individual post stroke potential" (Graven et al., 2013).

A previous study recommended rather than receiving all services and information in the earlier stages of recovery, participants believed a more staggered system would allow them to access information and guidance when they were ready and as it became relevant to them (Barker & Brauer, 2005).

Participant 41 discusses how she was discharged with no upper limb movement and minimal information about how to progress or help herself. All the improvement she has had has been through her own doing. Barker et al (2005) acknowledged that 'Finding out how to keep moving ahead' was a theme in their study (Barker & Brauer, 2005).

Education is an integral part of self-management programs, which are gaining an evidence base in stroke management (Boger, Demain, & Latter, 2015; Mawson et al., 2014). Self-efficacy could be important areas to assess in the stroke population. Self-efficacy is a person's belief in his or her ability to succeed in a particular situation. Self-efficacy can have an impact on everything from psychological states to behaviour and motivation (Jones & Riazi, 2011). The Stroke Efficacy Questionnaire may be one such tool available to assist in measuring confidence in functional performance and aspects of self-management (Jones et al., 2008).

7.5 Mixed Methods

The author is aware of no other studies, which have used a similar mixed methods approach to evaluate an intervention in long-term follow up of chronic stroke participants using FES. Many stroke intervention studies do use self-reported measures such as the SIS or Motor Assessment Log (MAL) alongside functional and impairment measures such as ARAT and FM.

7.5.1 Relationship between quantitative and qualitative findings

The quantitative results in isolation for this thesis are unremarkable. However, on an individual basis, small increases were seen in all measures in some participants between baseline and the end of intervention and further small improvements were seen at follow-up (see appendix 7), indicating some participants had maintained their functional and impairment level. The synthesis and comparison of quantitative and qualitative data across the two groups of individuals affords a much greater insight into upper limb recovery using an intervention such as FES. To illustrate this point four case studies are examined more closely.

Participant 54 demonstrated long-term positive outcomes across his measures. He was the lowest functioning and most impaired of the follow-up group within the Salford cohort. Over the follow-up period he demonstrated a 21% increase in ARAT score and 16% increase in FM-UE score. Although neither exceeded the minimally

important clinical difference (MICD) for the respective measures he described this as a significant improvement in his interview. He also highlighted other improvements, such as how the limb looks and feels to him. The degree of increase in his Canadian Occupational Performance Measure (COPM) score also illuminates the importance of focusing not just on the objective outcome measures. For the self-chosen activity of fastening buttons, his scores for performance and satisfaction at week 0 and 12 were all 1, however by week 64 his performance score had risen to 6 and his satisfaction score to the maximum of 10. This participant demonstrates that it is possible for a severely affected individual to make improvements in chronic stroke, and that FES can enable PwS to take part in active rehabilitation with their upper limb. It could be argued this participant would not have made these changes if he had not been in the FES group, as with his initial level of function he would have had significant difficulty performing functional tasks and being able to practice them without assistance. This category of patient has been highlighted in the literature as posing the most significant challenge to therapists trying to facilitate recovery of the upper limb (Barker & Brauer, 2005; Barker et al., 2007).

Three participants demonstrated a mismatch between their perceived recovery and their actual recovery. Participant 55 also had low baseline function and showed similar improvements in ARAT and Fugl-Meyer scores to those of participant 54, however does not report any real changes in her upper limb in that time period, demonstrating a mismatch between her quantitative and qualitative data. She does however perceive she is making changes in other areas of her recovery.

Participant 41 was the highest functioning of the follow-up group at baseline and made further improvement, however the changes in objective measures were not fully matched by her perception of changes in her upper limb recovery. Between weeks 0 and 64 she exceeded the MICD for both the ARAT and Fugl-Meyer with increases of 8 and 8 respectively, demonstrating a long-term positive outcome. She reported in her interview that she improved whilst she was in the study, but when asked at week 64, she felt she had gone slightly backwards. This was despite increase in her ARAT score by 5 between week 12 and 64, which was more than the increase of 3 she had over the initial intervention period. She reported frustration with the speed and quality of movement, describing it as 'clumsy' and 'not precise', with a lack of automaticity.

Similar findings are reported in a study where high scoring individuals on the ARAT and Wolf Motor Function Test (WMFT) still reported residual disability on the Functional independence measure and MAL (Dromerick et al., 2006). Quality of movement on the WMFT was not strongly associated with self-reported frequency and speed of movement on the WMFT (timed score) was not associated with self-reported frequency (MAL amount of use). Again, the mismatch between clinical measures and participants' perceptions is evident, as participant 41, despite scoring highly in the ARAT and FM reports issues with speed and accuracy of movement.

Participant 41 does cite being able to put a bobble in her hair as a significant functional real world change after the REAcH study, which she was still able to do at week 64. This change would not have been captured in objective measures, reinforcing the need for improved objective measures in upper limb interventions that translate into real world activities for the participant, and the need to set goals which are meaningful to the PwS. She described feeling let down by the services she had experienced and repeatedly referred to a lack of physiotherapy and greatly values the input of therapy. Participant 41 referred to physiotherapists as a personal trainer, and expressed the challenges of self-motivation when undertaking long-term rehabilitation. The participants in Barker's (2005) study agreed that attendance at therapy, whether it was one-to-one or in classes, helped to maintain the motivation to keep going (Barker & Brauer, 2005). The differences in motivational support between participant 41 and 51 highlight the need to individualise level of support.

Participant 51 came across as a highly motivated individual who was managing his own rehabilitation, without any direct professional input. His attitude is one of trying to improve, he does not feel he has plateaued yet and feels there are always things he can do to improve. He reported his upper limb had definitely improved in the last year, however although his quantitative results showed some increases, they did not exceed the MICD at any point and did not show the same degree of increase as participant 41. His COPM scores also did not show any significant changes, despite being self-selected goals. Quantitative measures tend to dominate stroke research and these measures did not show the improvement perceived by this participant. Findings from this study therefore agree with van Delden (2013) who suggests that the accurate perception of a meaningful change is independent of the severity of the neurological

deficit or side of stroke (van Delden et al., 2013). The author agrees with van Delden et al (2013) who calls for both capacity and self-perception measures to be used as primary measures along-side objective measures, with power calculations based on both and goals set that can be measured by both (van Delden et al., 2013).

7.6 Limitations

At the time of design and submission to the ethics committee, the REAcH study, was still ongoing. The REAcH results were found to have no significant differences between the intervention groups, although there were some changes at an individual level. Consequently, this impacted on the authors study as the results at week 64 were compared to those in the REAcH study.

The lack of pilot testing of involvement of PwS in the interviews was a weakness in the methods of this study. A pragmatic decision was made not to pilot the questions with actual participants as the potential participant numbers were low and limited by those who took part in the REAcH study. The richness of the data from any one of the participants would be lost, as pilot data would not be included in the study analysis. However, in hindsight some pilot testing would have helped to refine the data collection tool, and would have been a valuable learning process for the researcher.

There was a potential for bias regarding the interviews as the author conducted the interviews and had seen most of the participants throughout their involvement in the REAcH study, and so could have been perceived by participants as not truly independent from the study. However, the author aimed to reduce social desirability bias by explaining that all views were relevant and valid whether positive or negative. There were some negative views aired in the interviews, which provides some reassurance that participants were comfortable expressing their views. The author also had expert knowledge of the study and is an experienced neurological physiotherapist, so was well placed to pose questions about the interventions and upper limb recovery following stroke.

These were the authors first interviews for research purposes and the author agrees with reflection that it can take time to develop interview skills (Balls, 2009). Researchers should not assume that because subjective questioning and listening are skills required within physiotherapy that interviewing for research purposes is an extension of that process. The researcher did not transcribe the interviews; this was a pragmatic decision based on the amount of time available. The author in hindsight would have transcribed them after each interview to be able to learn from the interview and refine the draft interview guide further to strengthen the interview technique.

It is worth noting that the participants' opinions could not be taken to necessarily be representative of the wider stroke population, as they actively consented to an upper limb research study, which takes a certain level of interest and commitment.

7.7 Conclusion

There is an opportunity for voluntary-triggered FES to assist promotion of high intensity task specific practice, as part of PwS self-management, and provide accessibility to task practice via technology, especially for those with a more severe paresis. A new movement-triggered device was developed and trialled in the REACH study, in participants with upper limb impairment due to chronic stroke. In contrast to the promising results of a previous pilot study, no statistically significant differences were found between the FES group and the control/exercise group in any outcome measures, although small improvements were seen in both groups.

Studies of the long-term effects of FES have been limited both in time (up to 9 months post intervention) and scope (focusing only on quantitative outcomes). Therefore, this mixed methods study, commenced before the results of REACH were available, followed up a sub-set of participants in the REACH study at 12 months post intervention.

The first aim was to identify whether changes in impairment, function and Quality of Life seen during the REACH project were maintained at 12 months. Nine participants

were recruited (4 from the FES group and 5 the control/exercise group). As no between group differences were found in the REACH study, statistical comparisons of data between the 2 smaller groups in the follow up study were not explored and the 9 participants were analysed as a single group. This study found that the follow up cohort showed no statistically significant differences between weeks 0 and 12 (end of the intervention) in all but two domains, and therefore minimal change to assess maintenance of follow-up. The mean self-reported recovery domain score of the Stroke Impact Scale (SIS) improved from 51.7 to 64.2 ($p = 0.006$) and SIS participation domain from 52.4 to 66.7 ($p=0.03$), both were maintained at follow up. Some changes in study measures were seen at an individual level which, in cases were maintained, or showed continued improvement over the 12 month follow up.

The second aim was to investigate whether changes in outcome could be attributed to the nature of the intervention. This was not pursued.

The third aim sought to use qualitative methods to explore the experience of the participants' upper limb post stroke recovery, and specifically during the REACH study and the 12 month follow up period of this study. Semi-structured interviews were carried out and thematic analysis of the data revealed 2 themes: The experience of participating in the REACH study was mostly a positive one. In spite of usability and reliability issues with the FES device, the overall concept was good and specific benefits were reported to be attributable to FES. Prescription of task specific practice and time with a Physiotherapist had benefits for participants in the exercise group. The second theme found non-physical factors have a significant impact upon stroke recovery, which is "not just a physical process". Key factors are recovery status, attitude and education.

This is the first study the author is aware of to have conducted a 12-month follow-up on chronic stroke participants in an FES trial. The author is also not aware of studies in upper limb stroke which used qualitative methods within an RCT in order to assess participants' experiences of that RCT, as well as their stroke recovery experience. By using a mixed methods approach the researcher was able to illuminate the findings of the RCT, contribute to FES research knowledge, future design and development, and further our understanding of the experiences of the PwS.

A degree of mismatch between quantitative and qualitative measures was noted, in line with recent research. Future research should consider inclusion of qualitative outcome measures in addition to quantitative measures to fully evaluate the effect of any intervention. Measures in rehabilitation and research should reflect more than just objective findings and measures should be developed to pay more attention to what is meaningful to the PwS, assessment of non-physical issues by the rehabilitation team can help to guide interventions and shape individual rehabilitation programs. Considering the knowledge the PwS has is important, and education is key to assisting PwS in managing their own recovery. Further, in line with recent reports, future studies should consider the use of additional interventions to support domains other than the physical in order to maximise stroke recovery.

Appendix 1: Long Term Follow Up of Electrical Stimulation Studies

Author(s)	Year	Design	Participants	Type of FES	Intervention including the groups	Follow up	Outcome	Comments
Kraft, Fitts, Hammond	1992	Evaluation	n =18 Gender = Male (M) 11, Female (F) 7 Time since stroke mean = 25.9 months (chronic) Severity = mild, moderate and severe	Electromyography (EMG)-initiated electrical stimulation vs low intensity electrical stimulation Wrist extensors only	1 EMG-initiated electrical stimulation (ES) of wrist extensors (EMG-stim) 2 Low intensity ES of wrist extensors combined with voluntary contractions (B/B) 3 proprioceptive neuromuscular facilitation (PNF) exercises 4 No treatment 3 month intervention, 3x a week total 36 1 hour sessions	3 & 9 months	Fugl-Meyer (FM) scores of PNF group improved 18%, B/B 25% EMG-stim 42% All intervention groups showed a significant difference from pre-treatment to post-treatment and the improvement was maintained at 3 and 9 months follow up Grip strength improved in all treatment groups and was maintained at 3 and 9 month follow up. Control group showed no significant change in FM scores or grip strength.	Conclusion: Chronic stroke patients can achieve and maintain functional improvements especially by combining ES techniques with voluntary effort. Not multi-joint stimulation EMG triggered stimulation, has voluntary effort.
Powell, Pandyan, Granat, Cameron, Scott	1999	Randomised controlled parallel group study	n = 48 Gender = M/ F unknown for those who completed Time since stroke mean = 23.4 days (acute) Severity = mild, moderate and severe	Electrical stimulation (ES) 3 times 30 minutes daily for 8 weeks to wrist extensors	1 Electrical Stimulation (ES) + standard treatment 2 Control group - Standard treatment	24 weeks	Change in isometric grip strength was significantly greater in the ES group than the control group at the end of the intervention and at follow up. At the end of the intervention grasp and grip sub scores of the ARAT increased significantly in the ES group compared with the control group. In a subgroup of 33 patients with some residual wrist extensor strength at study entry, the total ARAT score at the end of intervention had increased by a mean of 21.1 in the ES group compared with 10.3 in the control group. At the 24 week follow up there were no significant differences between the groups.	Cyclic stimulation only. Grip strength was significantly better in the ES group than the control group and was maintained at follow up.

Author(s)	Year	Design	Participants	Type of FES	Intervention including the groups	Follow up	Outcome	Comments
Popovic, Popovic, Sinkjaer, Stefanovic, Schwirtlich	2003	Randomised single blinded study	n = 28 Gender not available Time since stroke = 7 days \pm 2 weeks (acute) Severity = mild/moderate	Neuroprosthesis forearm – opening, grasping and releasing functions	1 Functional Electrical Therapy (FET) High Functioning Group (HFG) 2 Control HFG 3 FET Low Functioning Group (LFG) 4 Control LFG 30 minutes a day for 3 weeks FET or Exercise only (control)	6,13,26 weeks	FET and control groups showed a recovery trend in all outcome measures. The gains in FET groups were much larger compared with the gains in control groups. The speed of recovery in FET groups was substantially faster compared with the recovery rate in control groups during the first 3 weeks (treatment). The LFG subjects showed less improvement than the HFG in both the FET and control groups. Gains were increased or maintained at follow up.	LFG had minimum of 10 to 20 degrees of wrist extension and thumb and 2 fingers extension of 10-20 degrees actually is quite good level of function
Mann, Burridge, Malone & Strike	2005	Randomised controlled pilot	n = 22 Gender = M 10 F 12 Time since stroke = 7.1 months (sub-acute/ chronic) Severity = moderate	Passive electrical stimulation. 2 channel Microstim 2 with surface electrodes. 1 channel – triceps, 1 channel – wrist and finger extension	1 Passive electrical stimulation group, increased from 10 to 30 minutes twice a day over 1 week, overall intervention for 12 weeks 2 Passive extension exercises of the elbow, wrist and fingers practiced daily for same time as group 1	3 months	Statistically significant between group differences in change in ARAT scores were shown between the 2 groups at 12 weeks ($p = 0.003$) and maintained 12 weeks after the intervention ($p = 0.012$). Both groups improved. There were no significant differences in sensation (measured by two-point discrimination).	Significant treatment effect of <u>passive</u> electrical stimulation over passive stretching exercises. Both groups improved.
Kowalczewski Gritsenko, Ashworth, Ellaway & Prochazka	2007	Single blind randomised comparison	n = 19 Gender = 10 M 9 F Time since stroke = 48 \pm 17 days (sub-acute) Severity = severe	2 channel stimulator wrist extension, push button initiated by participant or researcher. Workstation with instrumented objects	1 High-intensity FES-ET group received FES-ET for 1 hour a day on 15 to 20 consecutive workdays. 2 Low-intensity FES-ET group received 15 minutes of sensory electric stimulation 4 days a week and on the fifth day they received 1 hour of FES-ET.	3 and 6 months	Improvements in the Wolf Motor Function test (WMFT) were significantly greater in the high-intensity group (post-treatment effect size, .95) than the low-intensity group (post-treatment effect size, 1.3). The differences in MAL and FMA were not statistically significant. Significant difference seen at 3 months but lost by 6 month follow up.	Subjects in the high-intensity FES-ET showed significantly greater improvement in WMFT than the group performing low-intensity FES-ET. However, this was not reflected in subjects' self-assessments (MAL) or in their FMA scores, so the clinical significance of the result is open to debate. The workstation was deemed unsuitable to be transferred to patients' homes.

Author(s)	Year	Design	Participants	Type of FES	Intervention including the groups	Follow up	Outcome	Comments
Barker, Brauer, Carson	2008	Single blind randomised controlled trial	n = 33 Gender = M 22 F 11 Time since stroke = 3.8 years (chronic) Severity = severe	Stimulation was to triceps only and was initiated by the participant and adjusted automatically according to their success or not.	1 Sensorimotor Active Rehabilitation Training (SMART) Arm with EMG-triggered electrical stimulation 2 SMART Arm training only 3 No intervention (control) Training – 12 1 hour sessions 3x a week over 4 weeks at participant's home. £ sessions of 60 reps, other sessions 80 reps. SMART Arm – participant sat at a workstation, arm is strapped to splint that prevented active movement. This was mounted on a linear slide. Participants worked to reach a target line. Load could also be added. Seat belt used to reduce compensatory movements. There was continual visual feedback on progression.	2 months	Both SMART Arm groups demonstrated significant improvements in all impairment and activity measures after the training and at follow up. There was no significant difference between the 2 groups. There was no change in the control group. Distance improved by 33% and peak force by 49%.	SMART Arm can reduce impairment and improve activity with severe chronic participants. Highlights the benefits of intensive task-orientated practice with severe paresis. No voluntary movement other than elbow extension
Lin, Yan	2011	Single blinded, randomised controlled trial	n = 37 Gender = M 22 F 15 Time since stroke = NES group 43.5 (SD 25.2) Control group 41.3 (SD 26.5) (acute) Severity = severe (based on baseline FM scores)	Neuromuscular electrical stimulation (NES) 2 channel stimulator applied with surface electrodes to supraspinatus, deltoid and wrist extensors. 180 cycles per session	1 NES cyclic NES for 30 minutes, 5 days a week per week for 3 weeks. Participants focused on the movement induced during the treatment. No active involvement. 2 Control received no stimulation Both groups received the same standard therapy for 30 minutes, 5 days a week for 3 weeks.	1,3,6 months	Significant improvements were found in both groups in terms of Fugl-Meyer (FM) and Modified Ashworth (MAS) scores after the end of the intervention. FM scores were higher in the NES group than the control group ($p < 0.05$). The significant improvements persisted at the 1 month follow up. At 3 and 6 month follow ups the average scores in the NES group were significantly better than for those in the control group.	Passive electrical stimulation only, no voluntary effort. Effects persisted for 6 months

Author(s)	Year	Design	Participants	Type of FES	Intervention including the groups	Follow up	Outcome	Comments
Mann, Taylor & Lane	2011	Pilot study, longitudinal case series design. Non blinded.	n = 15 Gender = M 10 F 5 Time since stroke = 4.1 years (SD 3.6 range 1-13 years) Severity = moderate	Accelerometer-triggered Functional Electrical Stimulation (FES) Voluntary effort required to trigger the stimulation. 2 channel programmable stimulator (Odstock medical). Surface electrodes applied to triceps for elbow extension and wrist and finger extensors in the forearm.	1 group only. 2 weeks of exercise stimulation, then 10 weeks of triggered stimulation. Home programme of 2 sessions of 30 minutes a day for 10 weeks. Practice included reaching, grasping and releasing objects in sitting, standing around the home and as part of activities of daily living. The amount of ADL practice was left up to the participants.	3 months	The Action Research Arm Test (ARAT) score improved from 19 to 32 ($P = .002$); the MAS score for elbow, wrist, and finger flexor spasticity was reduced from 2 each to 1, 0, and 1 ($P < .05$); the Canadian Occupational Performance measure (COPM) performance and satisfaction scores improved ($P = .001$); and the Psychosocial Impact of Assistive Devices Scale (PIADS) became positive for competence ($P = .005$), adaptability ($P = .008$), and self-esteem ($P = .008$). Gains were maintained 12 weeks later. 100% compliance of the device.	Accelerometer-triggered electrical stimulation to augment task training for the hemiplegic arm is feasible and may improve functional ability and quality of life which may be maintained 12 weeks after treatment. Refinement of the triggering system needed
Tarkka, Pitkanen, Popovic, Vanninen, Kononen	2011	Randomised controlled trial	n = 20 Gender = M 13 F 7 Time since stroke = 2.4 ± 2.0 years (chronic) Severity = severe	4 channel stimulator programmed (Actigrip). Surface electrodes were placed to facilitate hand opening and closing used in tasks (forearm and hand stimulation)	1 Functional Electrical Therapy (FET) 2 Control group – conventional therapy group Each group had 2 daily sessions 5 days a week for 2 weeks. Each session 30 minutes separated by 4 hours. 17 \pm 3 sessions each.	6 months	Measure - Navigated transcranial magnetic brain stimulation system was used to assess cortico-spinal excitability. Hand function was measured with the WMFT Faster cortico-spinal conduction and newly found muscular responses were observed in the paretic upper limb in the FET group but not in the control group after the intervention. Behaviourally, faster movements times were observed in the FET group but not in the control group. Improvement after the intervention ($p < 0.01$) and continued to improve by the follow up ($p < 0.02$). Functionality scores improved FET 13% and Control 9 % and continued to improve by follow up but without significant distinction between the groups	Findings suggest voluntary training of the paretic hand and wrist augmented with individualized stimulation such as FET, may produce changes in cortico-spinal excitability.

Author(s)	Year	Design	Participants	Type of FES	Intervention including the groups	Follow up	Outcome	Comments
Knutson, Harley, Hisel, Hogan, Maloney, Chae	2012	Early – phased randomised controlled trial	n = 17 Gender = M 9 F 8 Time since stroke = CCFES group 95 ±58 days, Cyclic group 109 ±47 Sub-acute <or = 6 months Severity = Moderate/ mild (based on FM at baseline)	No more than 3 channels used per participant. Surface electrodes to the forearm and hand. Contralaterally controlled FES with a glove on the non-paretic hand	1 Contralaterally Controlled Functional Electrical Stimulation (CCFES) 2 Cyclic Neuromuscular Electrical Stimulation (NMES) Both 6 weeks, 2 x a week = 12 sessions of therapist guided functional task practicing a finger-movement control task for 15 minutes followed by 75 minutes of using the paretic hand to perform functional tasks. Also self-administered repetitive stimulated hand opening exercise daily at home – 72 sessions per group. Equal amount of stimulation between the groups	1, 3 months	At all post-treatment time points, CCFES produced larger improvements than cyclic NMES on every outcome measure. Maximum voluntary finger extension showed the largest treatment effect, with a mean group difference across the post treatment time points of 28% more finger extension for CCFES.	Results favour CCFE, but the sample size is small. Gains made and maintained at follow up.
Rosewilliam, Malhotra, Roffe, Jones & Pandyan	2012	acute	n = 66 Gender = M 44 F 46 (of original 90 recruited) Time since stroke = <6 weeks Severity = severe	Surface neuromuscular electrical stimulation (NMES)	1 NMES 30 minutes, twice a working day for 6 weeks, in addition to standardised upper limb therapy. 2 Standardised upper limb therapy	12,24,36 weeks	ARAT – not significantly different between groups 0-6 weeks, or at 36 week follow up Active range of movement at the wrist improved more in the treatment group than the control group, but the difference in improvement was not statistically significant at any time point Wrist extension strength and grip improved significantly in the treatment group over the study period, the effect ceased after withdrawal of the intervention.	Participants had no functional movement at outset. Significant differences were seen for wrist extension and grip strength but did not persist at follow up
Persch, Page, Murray Follow up to Page, Levin, Hermann, Dunning, Levine 2012	2013	Prospective, blinded, cohort, pre-post study	n = 24 Gender not available Time since stroke = 36.7 months (range 7-162) Severity = severe/ moderate	Bioness H-200 neuroprosthesis wrist and finger extension.	Repetitive task practice of valued activities and electrical stimulation (3 groups 30, 60 or 120 minute sessions, 4 th group home exercise programme those participants not included in this analysis) every week day for 8 weeks	3 months	Subjects maintained the functional abilities gained during the training period (see page et al 2012) 3 months later. No significant changes in any measure. Retention of changes across all outcome measures implies changes not just limited to 1 domain of movement, and more likely to impact on daily upper limb use. NB: significant score increases were seen only in the 120 minutes group in the original study.	3 month follow up of one group as part of a larger study. No details on which group the participants were in, in the original study

Author(s)	Year	Design	Participants	Type of FES	Intervention including the groups	Follow up	Outcome	Comments
Page, Levine & Basobas	2016	chronic	n = 9 Gender M 7 F 2 Time since stroke = 37.1months Severity = moderate	Bioness H-200 neuroprosthesis wrist and finger stimulation	1 group all received repetitive task practice and electrical stimulation 3 days a week for 120 minutes over 8 weeks, with the behavioural supports	3 months	Statistically significant increases on all measures at both time points comparisons. Measures – FM, Box and Block, Motor Activity Log. Subjects reported a new ability to perform valued activities they had not performed in months	Addition of behavioural supports to repetitive task practice augmented with electrical stimulation increased upper limb function and use

Appendix 2: REAcH Study Results Presentation

THE REACH PROJECT: A RANDOMISED CONTROLLED TRIAL OF AN ACCELEROMETER TRIGGERED FUNCTIONAL ELECTRICAL STIMULATION DEVICE FOR RECOVERY OF UPPER LIMB FUNCTION IN CHRONIC STROKE PATIENTS

PAUL TAYLOR, LAURENCE KENNEY, GERALDINE
MANN, CAROL MCFADDEN, JULIE ESNOUF, CHRIS
SMITH, KAREN WARING AND HELEN LUCKIE

UNIVERSITY OF SALFORD
AND
THE NATIONAL CLINICAL FES CENTRE, SALISBURY



INTRODUCTION

- Success of FES used as a training device and orthosis in the LL
- FES in the LL has demonstrated functional benefit and the ability for users to participate in higher intensity practice
- Aim was to replicate this in an UL take home device – to facilitate meaningful, task specific practice

“TRAINING ORTHOSIS” FOR PRACTICING REACHING AND OBTAINING OBJECTS

Target group

- Ability to make a grip but unable to release
- Restricted elbow extension
- Chronic stroke

Stimulation

- Wrist, finger and thumb extensors
- Triceps



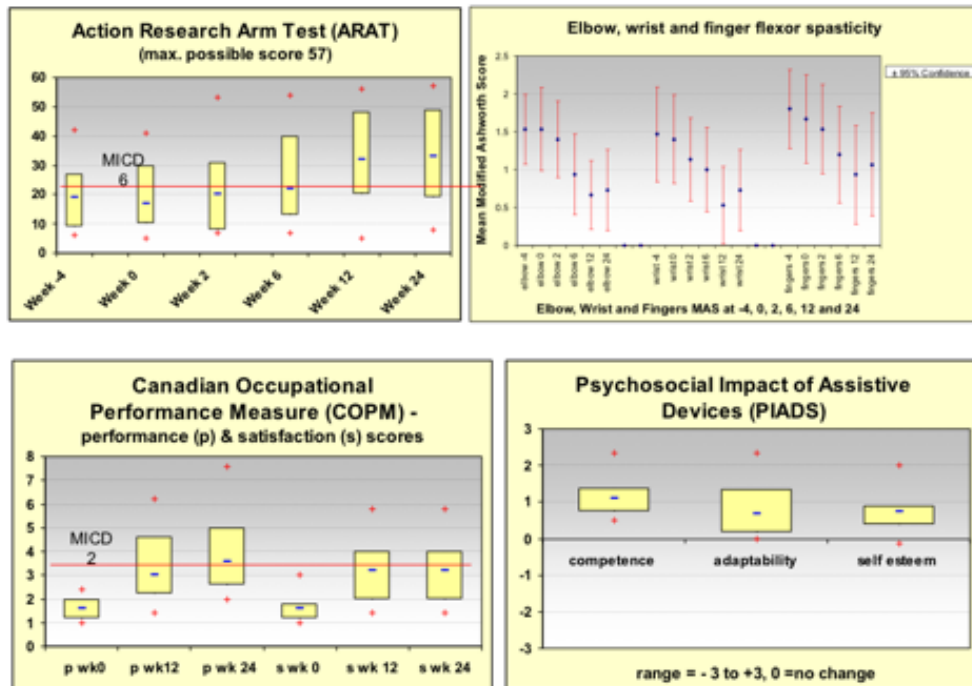
Stimulation triggered by movement sensor

- Assistance to reach and open the hand in response to attempt to make movement

PILOT STUDY

- Repeated Case Study design – 18 months
- 15 participants
- 4 week baseline
- 2 weeks exercise stimulation elbow, wrist & finger extension
- 10 weeks triggered stimulation for given functional tasks, use of system for practice of chosen ADL tasks & any other ADL desired by the participant
- Treatment withdrawn at end of this period
- 12 week follow up





USER REPORTS

- The reported time spent using the device each day was between 1-12 hours (mean = 3 hours) this was of triggered practice of given tasks, practice of their selected tasks in the COPM and other ADL's.
- Most users found the stimulation system easy to don and doff and the controls easy to use.
- All participants found the system useful to varying degrees: 3 fairly useful, 7 useful, 3 very useful, and 2 extremely useful.
- The trigger was not always effective and some participants at times used the system in exercise mode to assist with functional activities as well as during the prescribed exercise sessions.
- At end of study one volunteer made her husband a birthday cake - something she had not attempted since her stroke. She was also able to fasten the buttons on her jeans without help.
- A 2nd volunteer was able to hold his large camera steady with both hands giving him more control over the standard of his photographs, regain use of the controls on his car with his affected arm and hold a book and turn the pages when singing in his choir without needing a music stand.

RCT – The REACH Project

The same protocol except:

- 30 per group (60 in total) powered on ARAT
- Control group who performed the same exercises without FES assistance
- Base line 6 weeks not 4 weeks
- Blinded assessments
- Triceps stim combined with anterior deltoid
- Stimulator re-engineered to make set up easier
- Stimulator set up by Physio not Engineer
- Additional outcome measures
 - Fugl Meyer –impairment
 - Stroke Impact Scale – QOL
 - Box and block – hand function
- Salisbury and University of Salford

INCLUSION/ EXCLUSION CRITERIA

• Inclusion Criteria

- First stroke leading to hemiplegia
- Over 18 years of age
- and 6 months plus since stroke
- Medically stable
- Minimum of 45 degrees active shoulder flexion
- Able to initiate elbow extension
- Wrist and finger extension to pick up and release 2.5cm block
- Able to give informed consent

• Exclusion Criteria

- Pregnancy
- Poorly controlled epilepsy
- Cardiac pacemaker or implantable device
- Malignancy in the area of the electrodes
- Fixed contractures at elbow, wrist or fingers
- **To be discussed:** Diabetic neuropathy, painful shoulder, other neurological or orthopaedic conditions, communication and/or cognitive difficulties, current treatment with FES or Botox

METHODOLOGY

- **Week -6** Blinded outcome measures taken
- **Week 0** Blinded outcome measures, randomisation
Exercise gp- Physiotherapist taught stretches & exercises
FES gp – Device set up cyclic only, stretches & exercises
- **Week 2** Ex gp – exercises changed to voluntary exercises
FES gp – Triggered stimulation set up for unrestricted use of device in ADL's (visit with Physio)
- **Week 6** Physio review and progression both groups
- **Week 12** Intervention withdrawn. Blinded outcome measures and un-blinded measures taken with the device on for FES group
- **Week 24** Blinded outcome measures

- Phone and face to face support available throughout 12 week intervention

59 Recruited

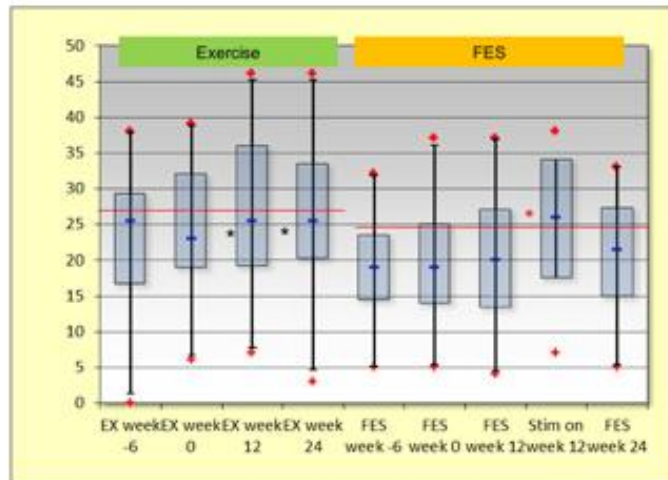
Exercise group
31

FES group
28

22 completed
protocol

22 completed
protocol

ARAT

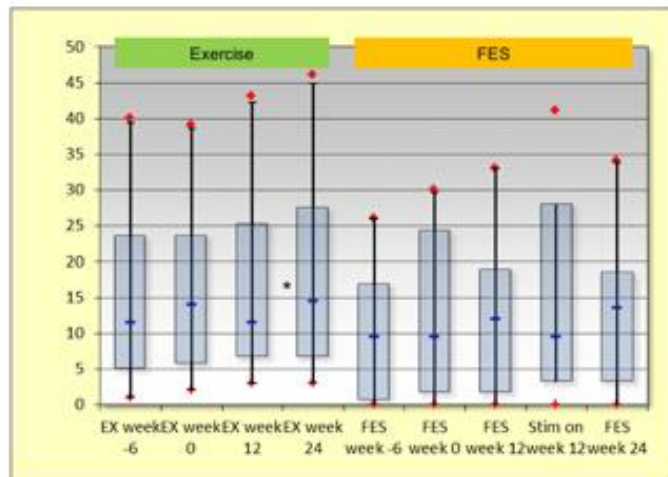


Exercise group: Improved ARAT but median below MICD

FES group: No Training effect. MICD when device switched on

No significant difference between groups

Box and Block

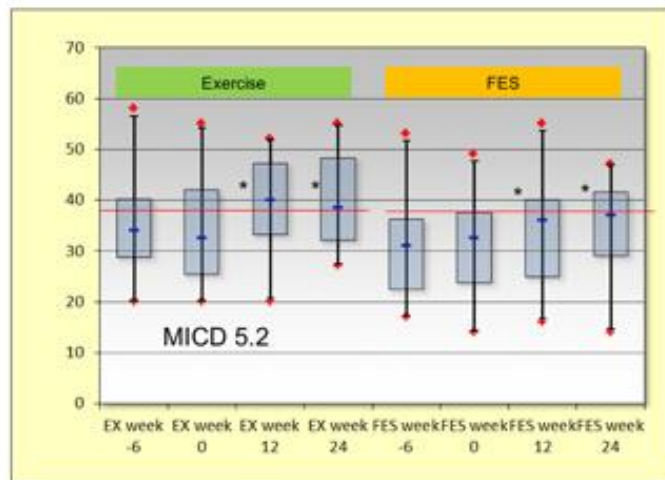


Exercise group: Small Improvement in B&B at week 24

FES group: No Training effect. No improvement when device switched on

No significant difference between groups

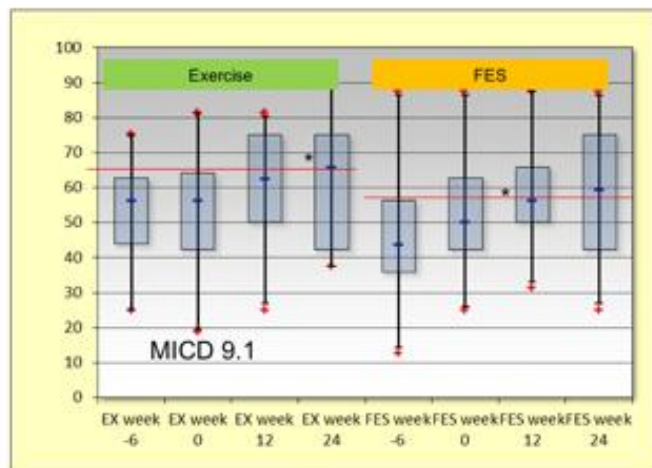
Fugl Meyer Total Score



Both groups showed reduced impairment

There was no difference between groups

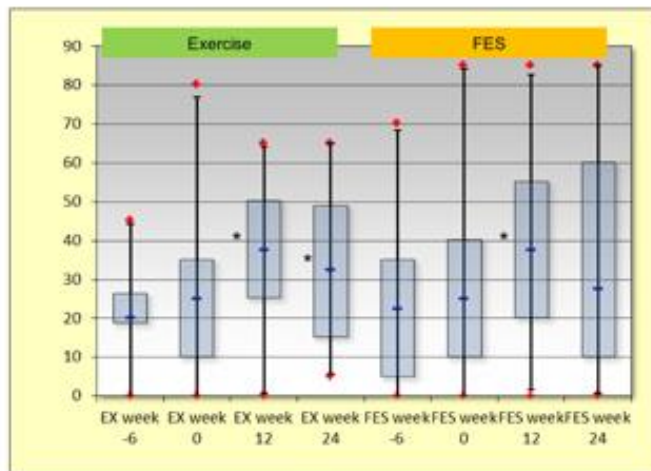
SIS Physical Problems



Both groups showed improved physical scores

There was no difference between groups

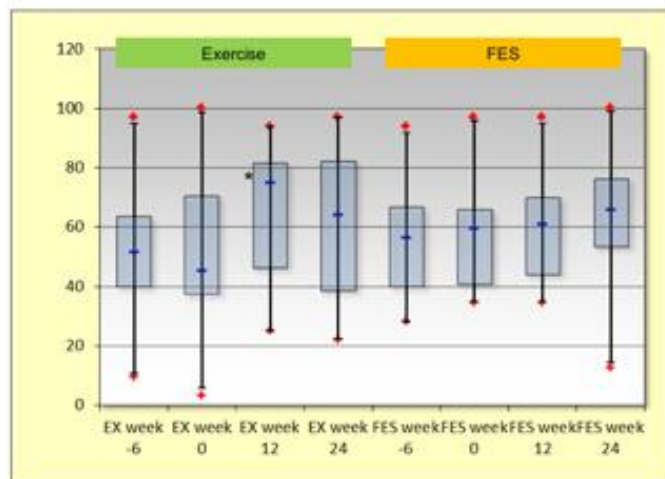
SIS Hand Function



Both groups showed improved hand function scores

There was no difference between groups

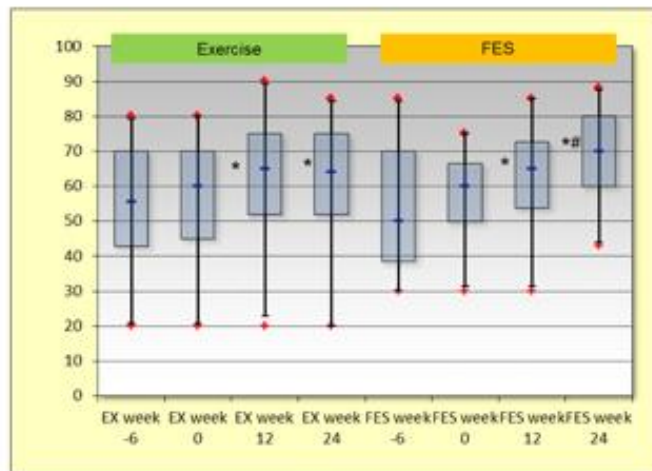
SIS Quality of Life



The exercise groups showed improved QoL scores at week 12

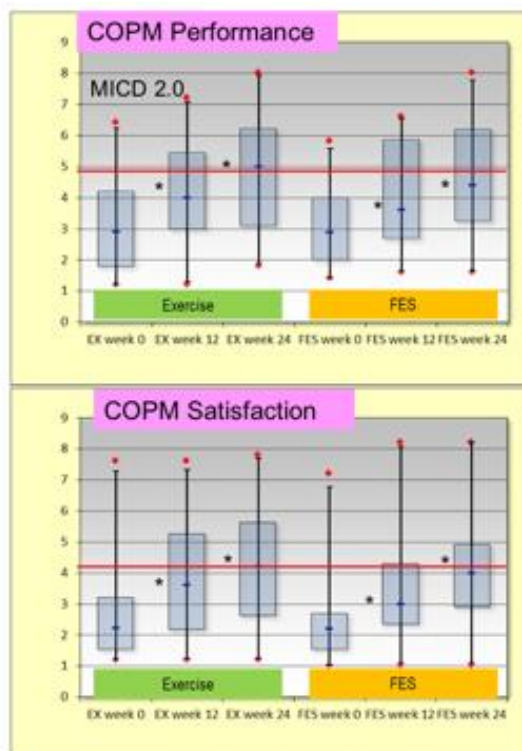
There was no difference between groups

SIS Stroke Recovery



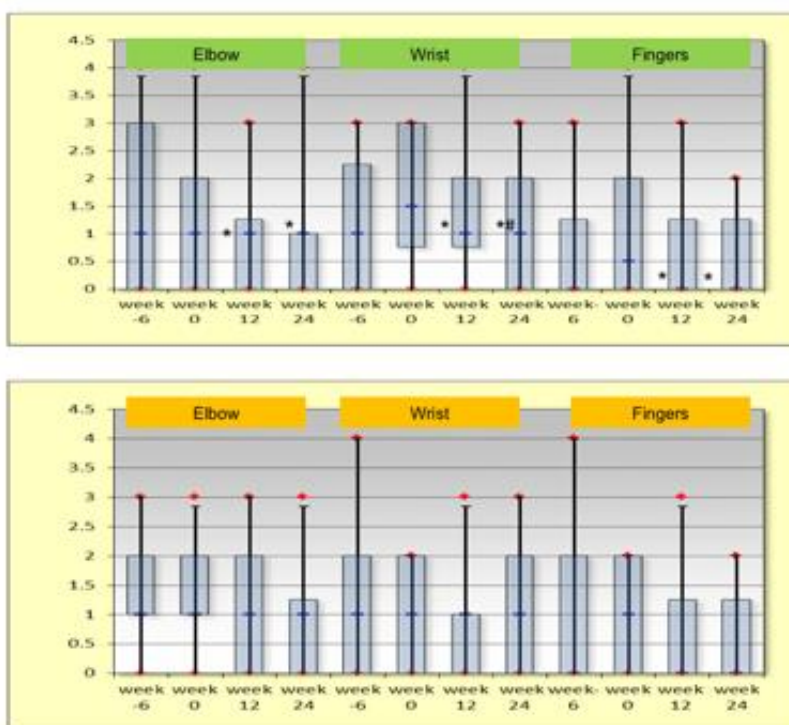
Both groups showed improved stroke recovery scores

This was greater in the FES group at week 24



Both groups improved COPM satisfaction and performance scores

There was no statistical difference between groups



Modified Ashworth Score

The exercise group showed small but statistically significant improvements in MAS

This was statistically significantly different at week 24 for fingers

The FES did not change

FES user feedback – Use of Device Questionnaire (n=24)

Usage

The device was reported as being used on a mean of 12 days in the last 2 weeks of the intervention, for a median of 85 minutes each day.

Benefits & Usefulness

19 out of the 24 participants reported at least one improved ADL

18 reported benefit from the device, 11 reported increased voluntary movement, 6 reduced spastic tone, 4 increased awareness of their affected upper limb and 3 increased use of their affected upper limb in bimanual tasks

6 participants reported the device was very useful, 6 useful, 6 fairly useful and 6 not useful for performing practical tasks

FES user feedback – Use of Device Questionnaire (n=24)

Usability

9 participants reported the device was difficult to put on, this was particularly the case when doing so without assistance.

13 participants reported difficulty correctly positioning the device and electrodes.

18 participants reported the device was comfortable to use.

Device Functionality

8 participants reported device failure, 3 reporting this was frequent.

7 reported the controls were difficult to use

8 participants reported that the device triggering was reliable and 8 triggering was OK, 9 experienced false triggering, of which 4 reported false triggering occurred whilst walking or using a mobility scooter.

There were some inconsistency in the hand movements produced by the device with only 5 reporting consistent movement.

CONCLUSIONS

- There was no significant difference between groups in almost all outcome measures
- Changes were significantly less than in the pilot study
- Participants reported benefits from the device, but there were user and reliability issues with device
- Improvements in device reliability are required

Appendix 3: Ethical Approval



Research, Innovation and Academic
Engagement Ethical Approval Panel

College of Health & Social Care
AD 101 Allerton Building
University of Salford
M6 6PU

T +44(0)161 295 7016
r.shuttleworth@salford.ac.uk
www.salford.ac.uk/

29 June 2012

Dear Helen,

RE: AMENDMENT TO REP11/057 – A 12-Month Follow Up to the REAch Study

Based on the information you provided requesting some further amendments to your original ethics application REP11/057, I am pleased to confirm that this has been approved by the College Research Ethics Panel.

If there are any further changes to the project and/ or its methodology please inform the Panel as soon as possible.

Yours sincerely,

Rachel Shuttleworth

Rachel Shuttleworth
College Support Officer (R&I)

Appendix 4: Participant Information Sheet



Centre for Health, Sport and Rehabilitation Sciences Research,
The University of Salford, Allerton building,
Salford, Gtr Manchester
M6 6PU United Kingdom
Telephone: 07791-444669
E-mail: h.m.luckie@salford.ac.uk
Web: <http://www.healthcare.salford.ac.uk/research/>

PARTICIPANT INFORMATION SHEET

11th June 2012 V1.5

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Project title: A 12 Month Follow Up of the Re-education of Arm and Hand function following stroke (REACH) Randomised Controlled Trial.

A short title for the project is: A 12 Month Follow Up to the REACH Study

What is the purpose of the project?

As you may remember, you kindly participated in the REACH study, which took place here at the University of Salford almost a year ago. In the REACH study we were interested in whether or not a new treatment (functional electrical stimulation) improved arm and hand function following stroke. We compared the new treatment with a conventional treatment (physiotherapy) to see if there were differences. We took measurements up to 3 months after the end of the treatment. We have now completed the study and anticipate completing the analysis of the results in the next few months. We will be sending you a summary of these results in due course.

Although we will shortly find out whether or not the new treatment was more effective than the conventional treatment over a relatively short time period, it is also of interest to see if improvements are maintained over a longer period. There is new evidence showing that in certain circumstances this may be the case and we would like to take the opportunity to investigate this question.

The new study that is described in this Information Sheet therefore investigates whether the new treatment used in the REACH study has effects on the arm or hand that last for 12 months and whether these effects are different to those seen in the group who received the conventional treatment. We also would like to find out if we can predict these effects from measurements we took in the REACH study.

Why have I been sent this information?

You have been invited to take part in this study as you volunteered and completed the REAcH – Re-Education of Arm and Hand function following stroke research study that was conducted at the University of Salford.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be able to keep this information sheet and will be asked to sign a consent form. If you decide to take part, you are free to withdraw at any time and without giving a reason. Should you decide to withdraw from the study any data collected will be destroyed. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of any care you receive in the future or from the NHS.

How long will I be involved with the project if I take part?

The study involves a single visit to the University of Salford, lasting approximately 2 hours.

What will happen to me if I take part?

Unlike in the REAcH study, you will receive no additional treatment as part of this study.

If you decide that you would like to take part in this study, the researcher will firstly contact you by the method of your choice to ask you a few questions about any changes to your medical condition which may affect the outcome of the study. If appropriate, we will then invite you to visit the University at a time and date that suits you. I will then check you have had the opportunity to read and consider this information sheet and check your understanding of the study, and answer any queries you may have prior to asking you to sign a consent form. You will be asked to sign 2 consent forms so that you may keep one for your records.

The visit will last approximately 2 hours and you would be welcome to bring someone else with you if you wish.

During the visit you will be asked to carry out a questionnaire and arm and hand tests, all of which you will have completed previously within the REAcH study. With your permission these will be video taped to enable the results to be checked and to be potentially used in presentations of the results of the study. As a reminder, here is the list of the tests:

- Two practical tests of how you use your hand and arm
- A physiotherapy assessment of the spasticity and stiffness in your hand and arm
- A standard measure of strength and movement in your upper limb
- A standard questionnaire-based measure of the impact of stroke on quality of life
- A measure of how you make use of your arm in everyday life

Most of the outcome measures will be performed by a clinician who should not be aware of what sort of treatment (physiotherapy or the stimulator) you received in the REAcH study. This is so they can make the assessments without being influenced by this information. It is **very important** that you do not tell the clinician the type of treatment you received as part of the REAcH study.

Following this you will be asked to take part in a short interview with the researcher to discuss aspects of your arm and hand recovery in the last year since you were involved in the REAcH study. With your permission we would like to tape record the interview and make a few written notes as needed to enable the researcher to capture what is said. The interview will take approximately 15 -20 minutes, although you will be free to pause or stop the interview at any time. All interviews will be typed up and a copy sent to you to check and keep. It is up to you whether you are interviewed on your own or whether you wish to have someone else with you.

What clothes should I wear?

Wear what you feel comfortable in; we will be assessing your arms so a loose, sleeveless or short sleeved garment would be ideal.

What facilities does your department have?

There are disabled parking facilities outside the department. Within the department there is a toilet suitable for wheelchair users. We will provide refreshments as required. Chaperones will be provided as necessary, although as above you are free to bring someone with you to the visit.

What are the possible disadvantages and risks of taking part?

The only expected risk to taking part in the interview concerns the potential for upset when discussing your experiences of your arm and hand recovery. I am an experienced neurological Physiotherapist so should you become upset, I will be able to support you. If appropriate the interview will be paused or stopped although you can continue if you wish to.

What are the possible benefits of taking part?

It is unlikely you will personally benefit from taking part in the study, however you may find the opportunity to discuss your arm and hand recovery beneficial. We hope the findings from this study will help inform about the effectiveness of the treatments in REAcH to assist recovery of arm and hand function after stroke.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you may complain to the University of Salford.

Will I be paid for participating?

You will not be paid for participation. However, we will be able to reimburse reasonable travel expenses.

Will my taking part in this project be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential. Each participant on the project will be given a unique code that does not contain any personal details such as names and addresses. All data collected will be anonymised and confidentiality will be maintained at all times. Interview tapes will be destroyed at the end of the study. If you take part in an audio-taped interview, you will not be identifiable from any presentation of findings as written quotes will be used that are fully anonymised. If you agree for the practical tests to be video taped you will be identifiable and this may be used in presentations of the findings of the study eg: at conferences and feedback events, as your face will be seen. If you wish to view any video clips before they are used please make this known to me and I will arrange this with you.

What will happen to the results of the research project?

The results may be used for planning future research. Findings may also be published in scientific and medical journals, at conferences and at training days for clinicians. Confidentiality and patient anonymity will always be maintained. If you are interested, we would be pleased to discuss the results and conclusions from the project with you. A summary of the results will be sent to all participants for their information.

Who is organising and funding the research?

The travel costs of the participants are being funded by the University of Salford. The researcher is a post graduate student at the University of Salford.

Who has reviewed the project?

The study has been reviewed by the University of Salford Research Ethics Panel (REP).

What do I do now?

If you would like further information or would like to take part please contact the researcher. If I have not heard from you within 2 weeks of this invitation being sent, I will contact you by phone to clarify whether or not you would like to participate.

: **Helen Luckie** Research Physiotherapist/ Post graduate student

0161 295 7039 or on email h.m.luckie@salford.ac.uk or at

Helen Luckie
Centre for Health, Sport and Rehabilitation Sciences
Allerton Building
Frederick Road Campus
University of Salford
Salford M6 6PU

Thank you for reading this information sheet.

Appendix 5: Participant Consent Form

CONSENT FORM



Title of Project: A 12 Month Follow Up of the Re-Education of Arm and Hand function following stroke (REACH) Randomised Controlled Trial

Please initial box

1. *I confirm that I have read and understand the information sheet dated 11th June 2012 for the above study and have had the opportunity to ask questions.* ☐
2. *I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.* ☐
3. *I understand that at the end of the study data collected from me will be stored at the University of Salford in line with the institutional guidelines for good clinical practice in research and in line with the policies for postgraduate research.* ☐
4. *I am/am not participating in another study at this time (delete as appropriate).* ☐
5. *I agree that I will be videoed in the study and I agree that the video will be used for teaching and scientific conferences.* ☐
6. *I agree to take part in a tape recorded interview.* ☐
4. *I agree to take part in the above study.* ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Researchers copy

Appendix 6: Interview Guide

A 12 Month Follow up to the REACH study: Semi-structured Interview Guide

1. Therapy services contact

Has the participant seen a therapist since involved in REACH (approx. in the last year)?

If YES prompt for information – what profession, NHS/ private, how it came about referral or self-referral, frequency, duration, content.

2. FES

What group were they in? Have they investigated FES since being in the REACH study?

If NO – why

If YES – details, UL/LL, NHS/private, device, how is it going?

What did they think to the REACH device? Was it useful? How easy to don/ doff? Reliability? Triggering? Did they feel they benefitted from it? Anything specific? What could improve it, design ideas?

3. Arm and hand recovery since REACH

Do they feel their arm and hand are worse, same or better in the time since REACH? Why?

Prompt for specifics, what functional task has changed?

Do they feel the change is related to the study and why?

Functional use: Are they using it more, same or less since being in REACH? Specifics. Why?

Is this related to being in the study?

Are they aware of 'use it or lose it'? talk about automatic use

Taking part in the study: Do they feel they benefitted from taking part in the study, whatever group they were in.?

If YES – why, specifics, changes to functional tasks, ADL, behaviours, habits, attitude?

Recovery status/ journey – overall: Prompt to talk about their current recovery status now and their overall journey. What does recovery mean to them? Prompt to look back at their abilities just after their stroke to

now. Life after a stroke in terms of their UL and broader. Their perception of recovery and what it is to them.

Therapy input: How much input, what kind of input for UL over whole time course of their stroke? What was good, what was not? What would they change? What should UL rehab be like? What advice would they give others?

4. Facilitators and barriers to recovery

Help recovery: What has helped / facilitated their UL and overall recovery?

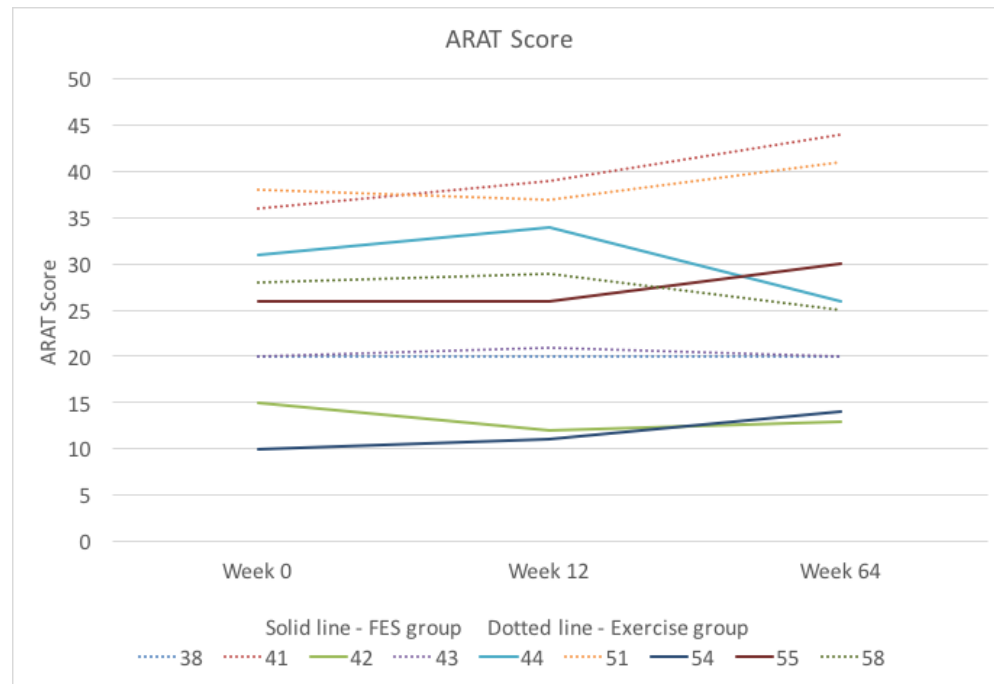
Prompts – services, people – friends and family, therapy, attitude, religion, approach, self- help strategies, their philosophy. Consider internal and external influences.

Barriers to recovery: What has been a barrier / hindrance / difficulties / made it hard/ stood in the way of their UL and overall recovery

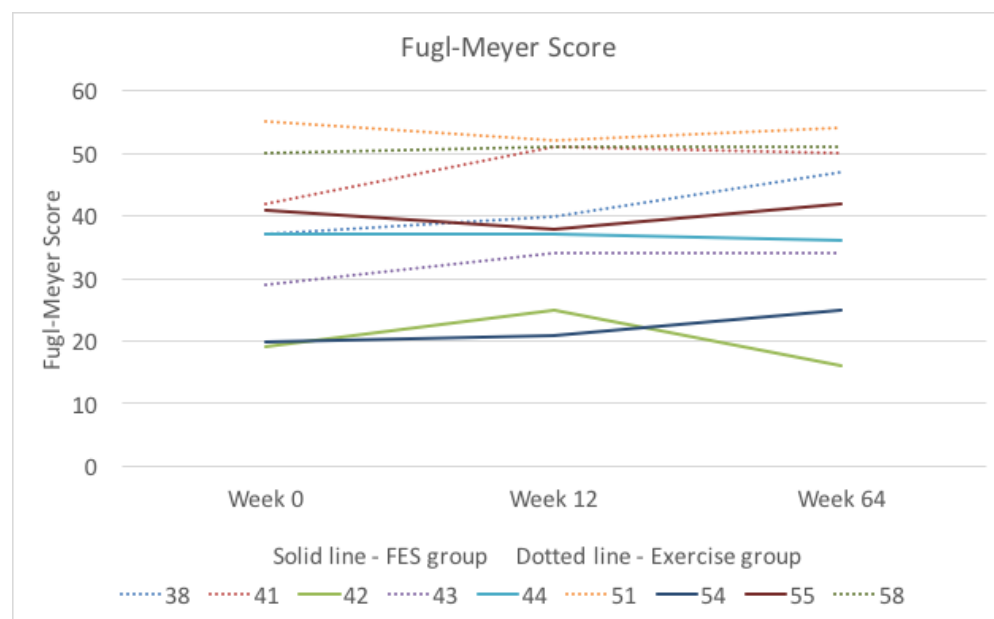
Prompts – services, people – friends and family, knowledge, information, consider internal and external influences.

Appendix 7: Individual Participant Results

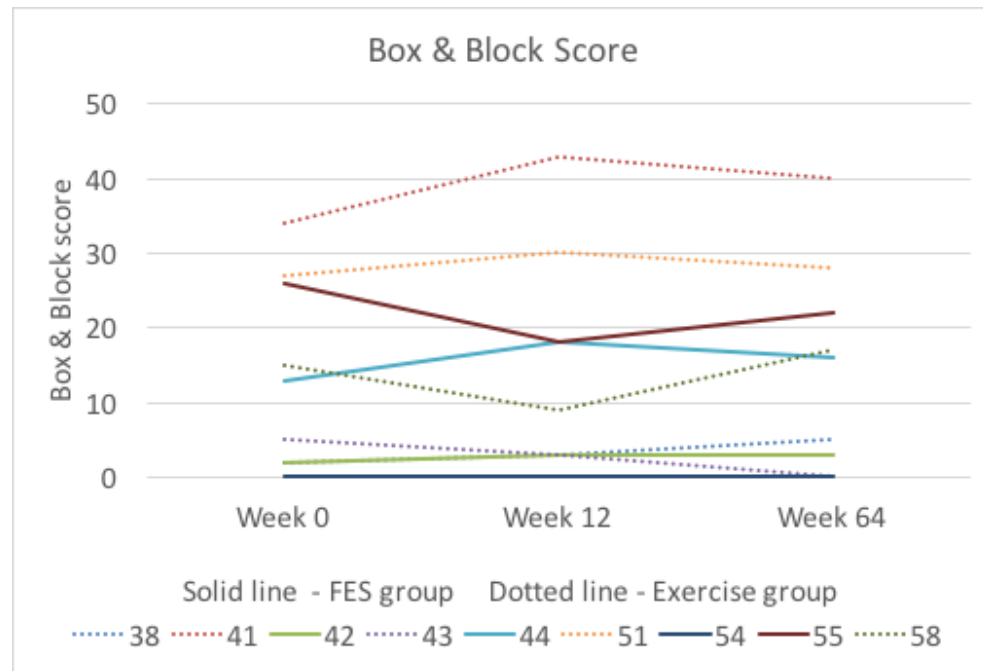
ARAT score



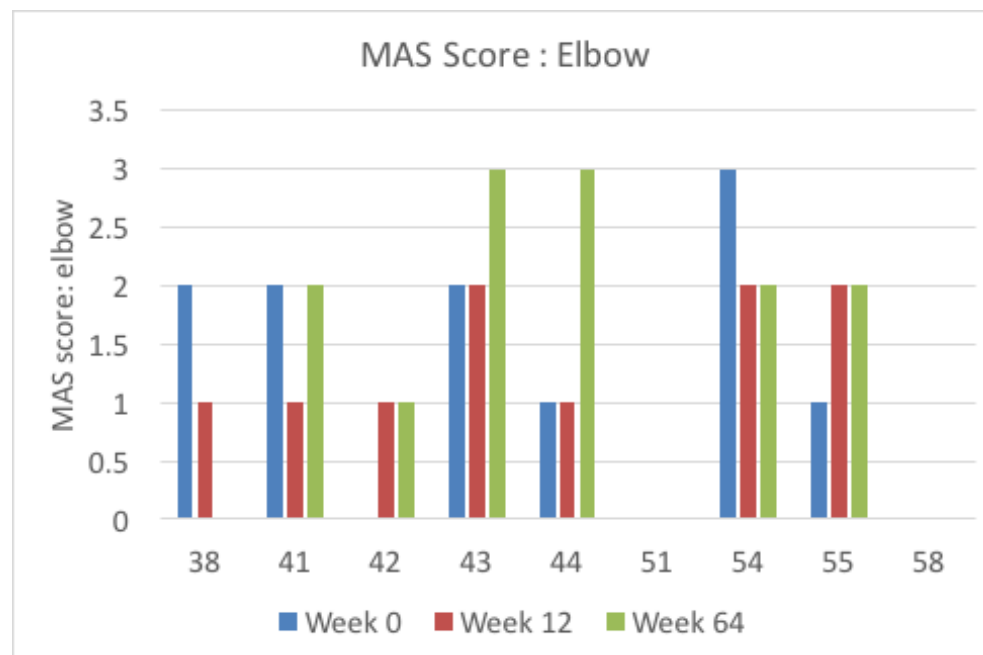
Fugl-Meyer score



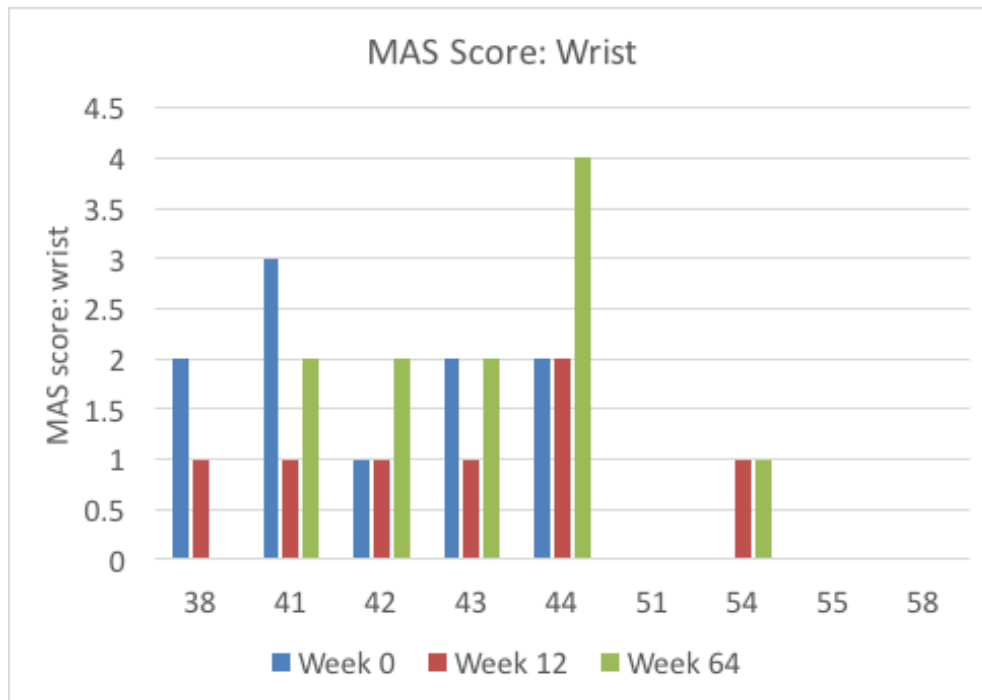
Box and Block score



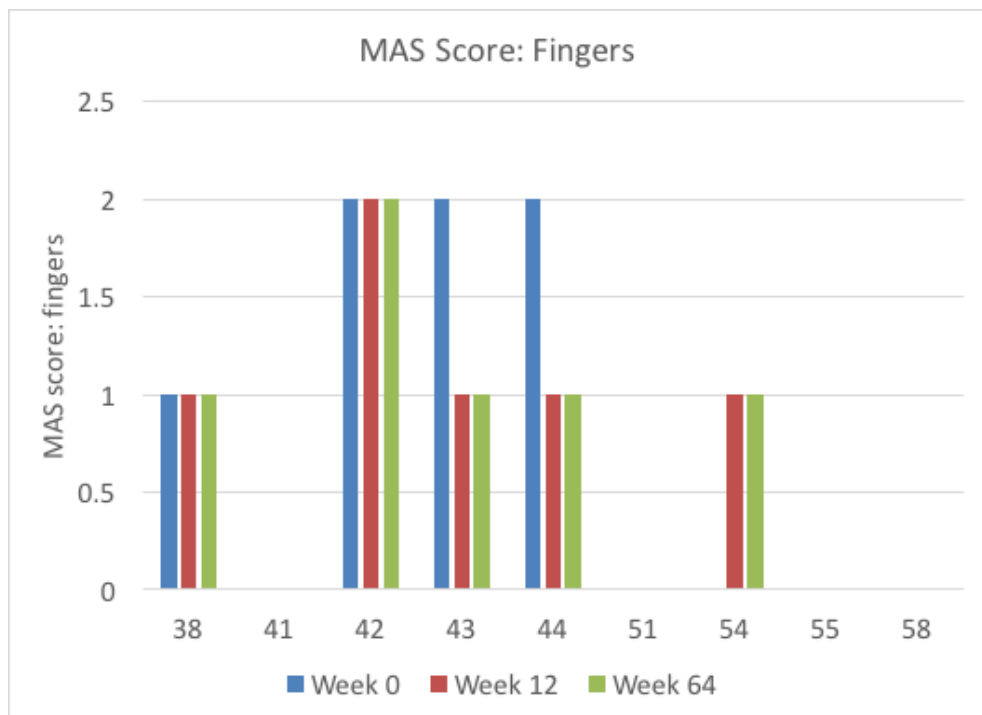
MAS score: elbow



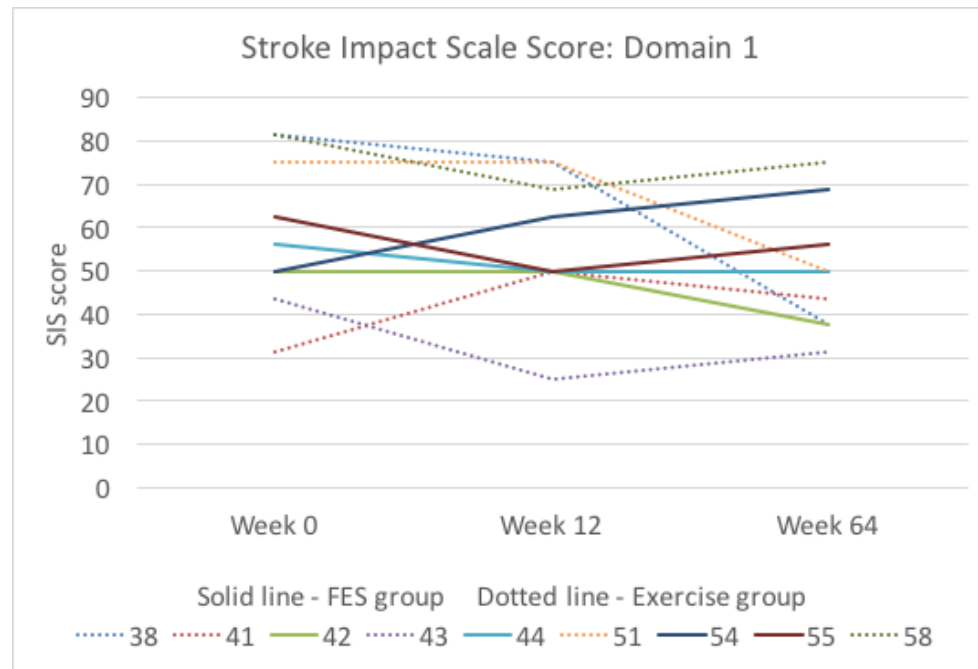
MAS score: wrist



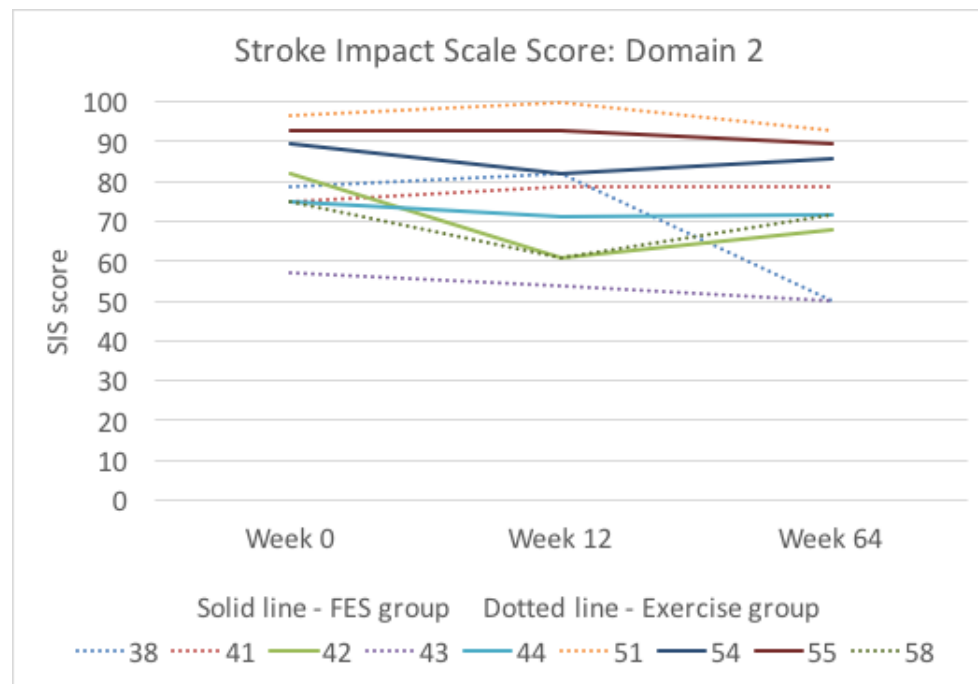
MAS score: fingers



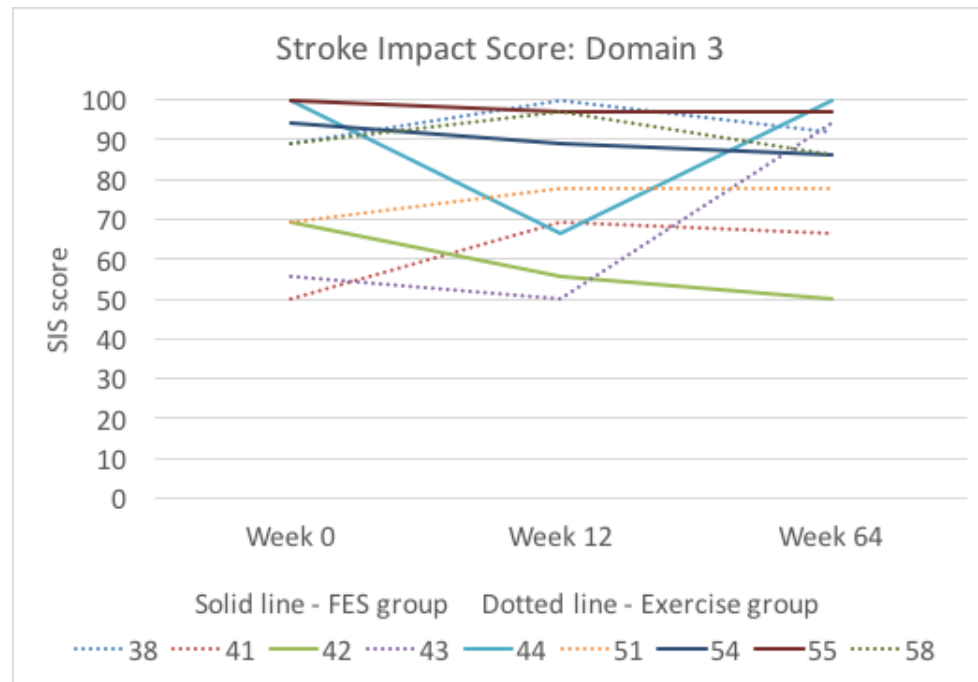
Stroke Impact Scale score: domain 1



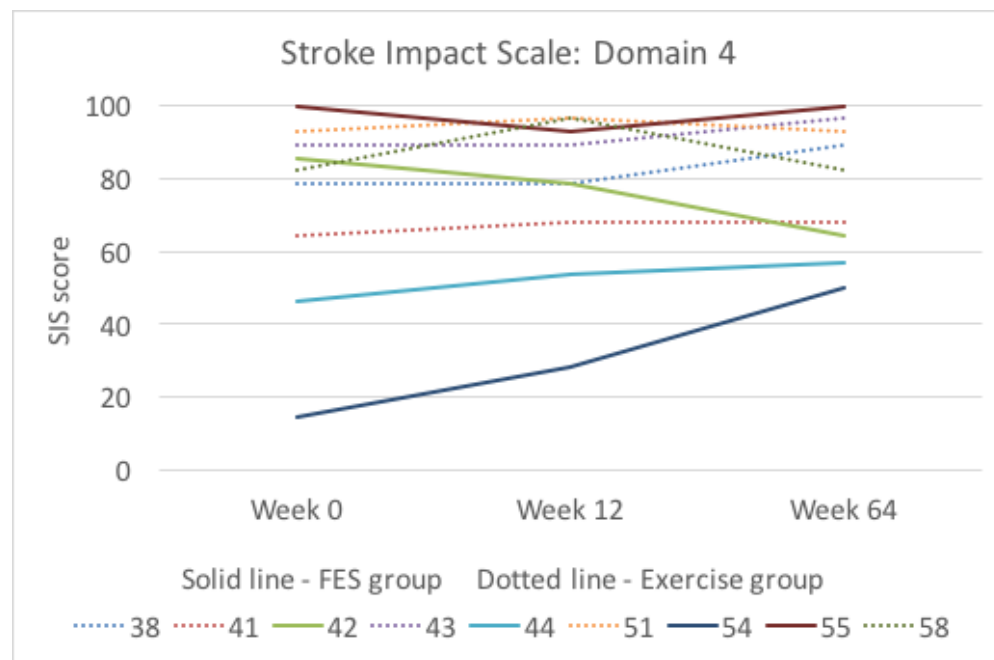
Stroke Impact Scale score: domain 2



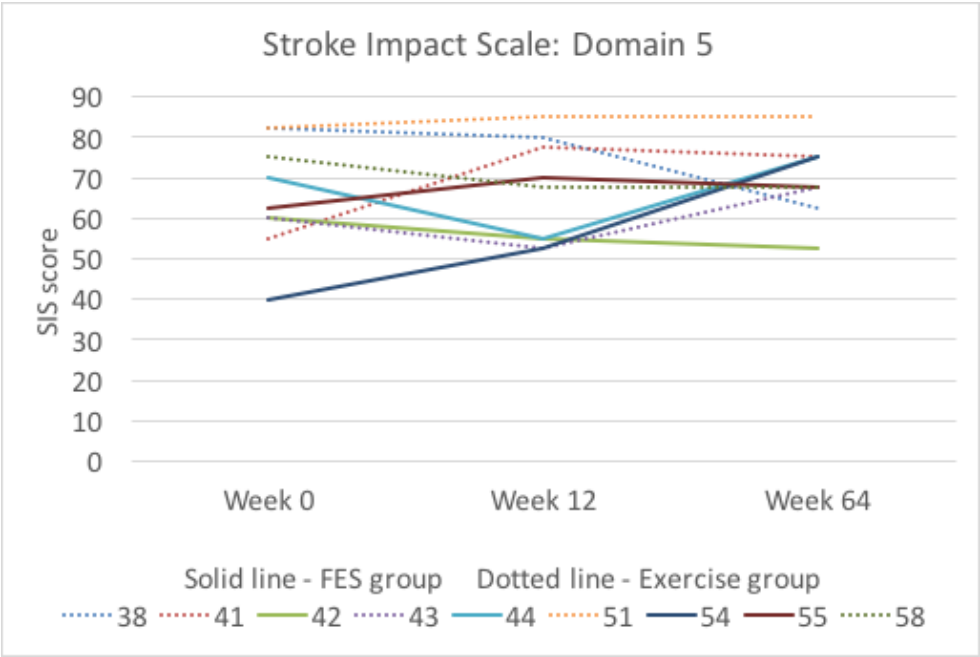
Stroke Impact Scale score: domain 3



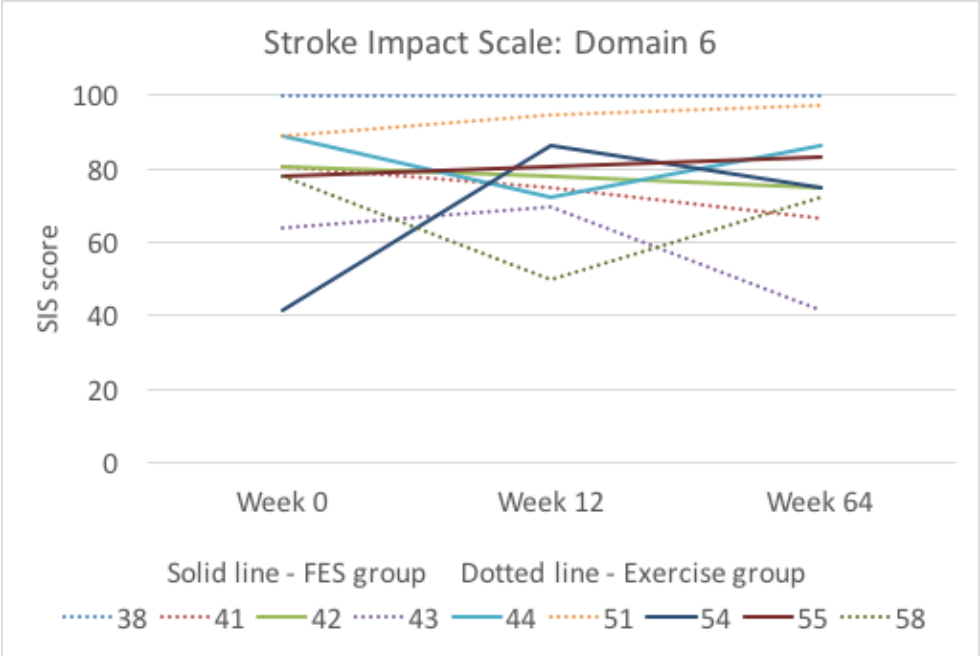
Stroke Impact Scale score: domain 4



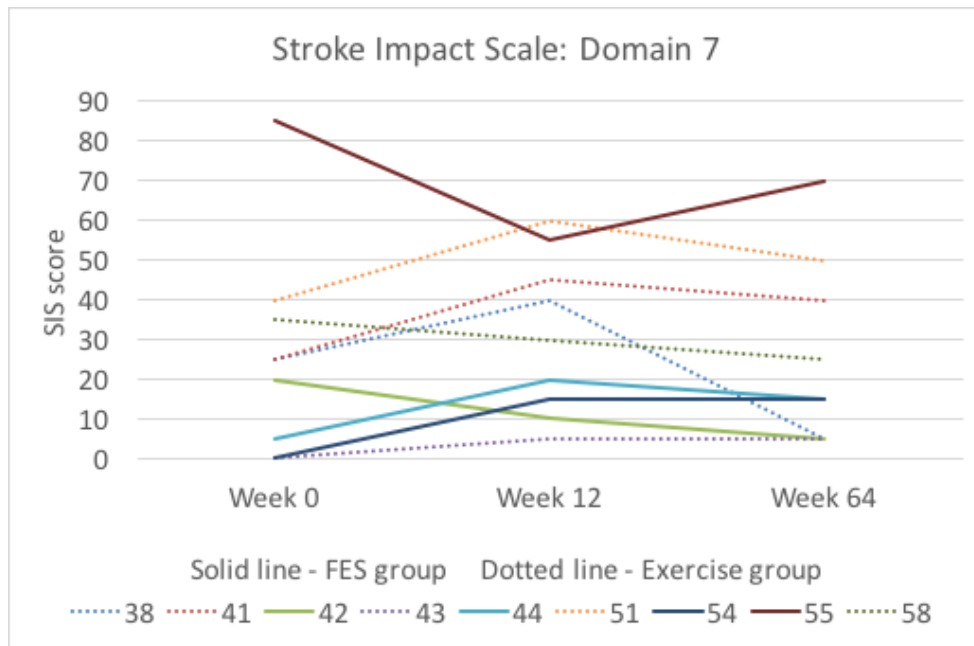
Stroke Impact Scale score: domain 5



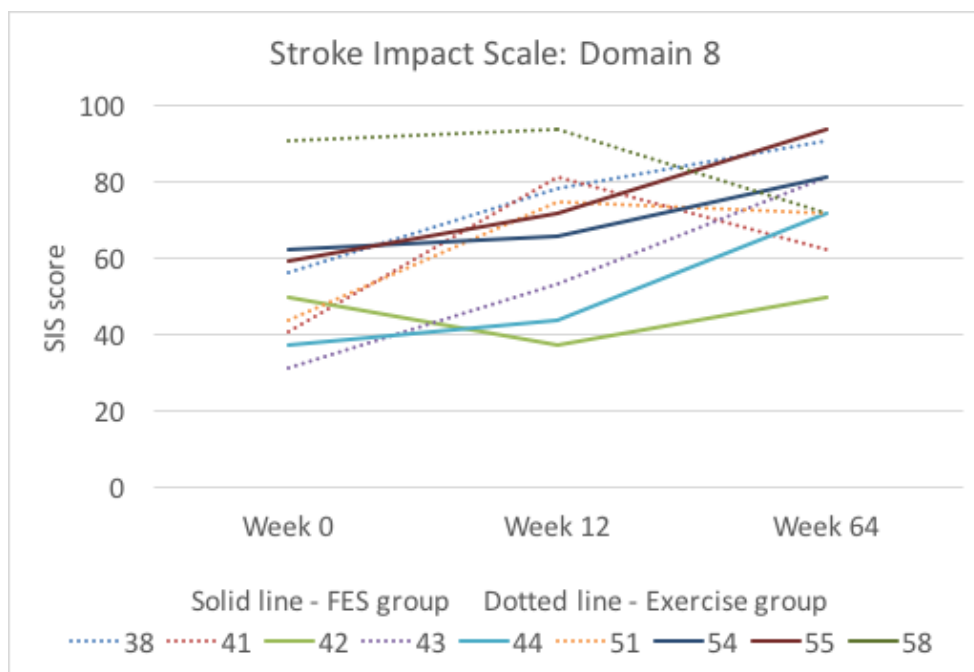
Stroke Impact Scale score: domain 6



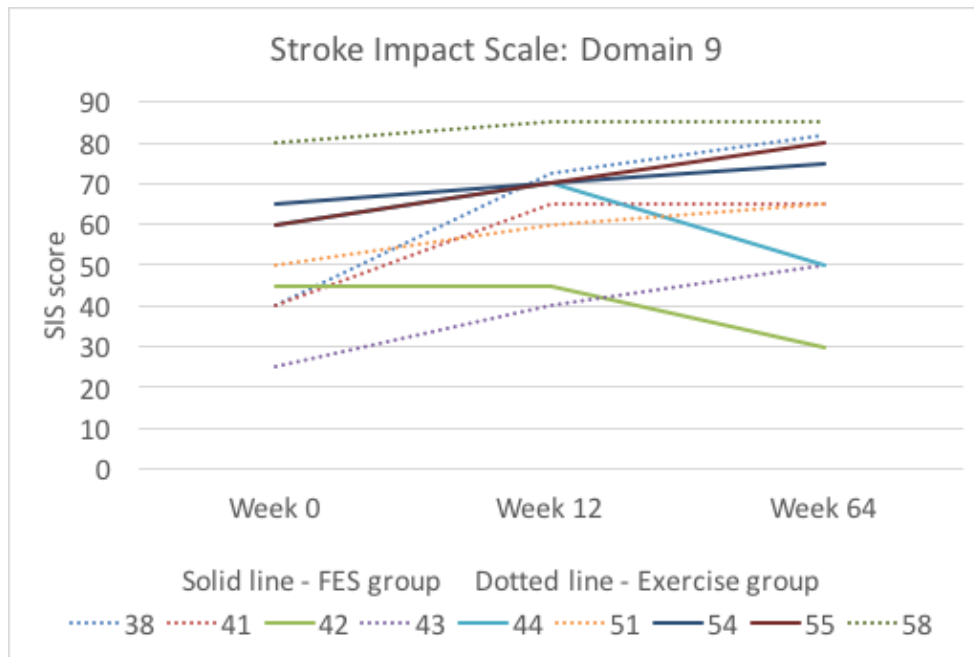
Stroke Impact Scale score: domain 7



Stroke Impact Scale score: domain 8



Stroke Impact Scale score: domain 9



Canadian Occupational Performance Measure (COPM) Results

The following demonstrated the COPM data that was collected, there is missing data for some of the participants.

Participant 38:

	Week 0		Week 12		Week 64	
Problem	P	S	P	S	P	S
1. Raise & lower into bath	1	1	1	1	1	1
2. Using hoe on allotment	6	3	6	3	1	1
3. Loading washing machine	3	2	3	2	10	10
4. Using right arm in washing & bathing	6	3	6	3	8	3
Score = Total P or S /no of problems	4	2.25	4	2.25	5	6.25

Participant 51:

	Week 0		Week 12		Week 64	
Problem	P	S	P	S	P	S
1. Turning car key in ignition	3	2	6	6	/	/
2. Using knife in left hand	4	2	5	5	6	5
3. Pegging washing out	6	4	7	6	8	6
4. Buttering bread / slicing veg	5	5	5	5	8	6
5. Playing golf	3	3	5	5	6	5
Score = Total P or S / no of problems	4.2	3.2	5.6	5.4	7	5.5

Participant 54:

	Week 0		Week 12		Week 64	
Problem	P	S	P	S	P	S
1. Fastening buttons	1	1	1	1	6	10

Participant 55:

	Week 0		Week 12		Week 64	
Problem	P	S	P	S	P	S
1. Washing self	8	8	8	9	10	10
2. Drying self	5	8	8	9	10	10
3. Exercising to music	5	6	8	9	10	10
4. Opening tins/cans	5	7	5	7	4	4
5. Fastening bra with 2 hands	1	7	1	7	1	1
Score = Total P or S / no of problems	4	7.2	6	8.2	7	7

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